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Valuing Intellectual Property Rights in the Life Sciences Sector: the Ozempic Case Study

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To my parents Vito and Arianna, to Philippa, to Nicolò and Brandon.

Thank you for supporting me and cherishing me in every step of my life,
and even in the toughest moments you never let me walk alone.

I'm forever grateful.

Introduction

Intellectual Property Rights ("IP rights") play a fundamental role in fostering innovation across an increasingly knowledge-based economy. Specifically, Intellectual Property Rights grant means of value creation for firms operating in highly technological sectors. If from a legal standpoint, Intellectual Property Rights constitute a source of protection for the invention of the human mind, granting exclusive rights for the Originators, compensating them for their efforts towards innovation; IP rights conceived as business assets, represent a source of competitive advantage, as the legal rights stemming from them constitute barriers to entry for potential competitors, preventing them to access to the protected technology or know-how. Specifically, in capital intensive sectors, such as in the case of the Life Sciences Industry, Intellectual Property represents one of the most valuable assets, since it can grant even direct way to monetize from the technological products deriving from the infinite R&D pipelines. R&D processes in the Life Sciences Industry are particularly long and require a significant number of investments, being ultimately exposed to several risks of failure, most specifically within the clinical trial phase: from thousands of potential molecules screened, only one chemical compound enters the clinical trial stage. Intellectual Property, as in this case patents, can grant ways for Life Sciences Firms to secure their R&D investments and defend the derived chemical compound or its clinical application, from potential reverse engineering of generic competitors.

Although Intellectual Property is among the most valuable assets for firms operating in highly innovative industries, such as Life Sciences, its value often cannot be reflected in financial statements. International accounting standards do not permit the inclusion of internally generated intangible assets on the balance sheet, and intellectual property rights are largely internally generated, particularly in the Life Sciences sector where investments in R&D pipelines are significant. Nevertheless, for intellectual property rights arising from the acquisition of a target, or in cases where they are recognized for accounting purposes, estimating their Fair Market Value becomes crucial: both from a transactional perspective, as in the case of Purchase Price Allocation ("PPA"), and from an accounting perspective, as in the case of impairment tests. The valuation of Intangibles, such as Intellectual Property Rights, is characterized by the lack of physical presence, and the magnitude of future economic benefits is characterized by a higher degree of uncertainty with respect to Tangible Assets. For this reason, the debate on valuation methods of Intangibles is currently lively,

with extensive academic literature taking multiple, often contrasting, viewpoints, such as in the case of the discount rate to be used to discount the future economic benefits related to Intangibles. Over time, multiple valuation methods have emerged, each characterized by fundamental theoretical assumptions to justify the selected methodology. Therefore, a careful choice in evaluating an intellectual property asset is crucial to authentically capturing its future economic benefits, which involves having a clear understanding of the type of intellectual property under assessment.

In the past, the crucial role of intellectual property rights has been demonstrated in defining the business model and contributing to the future economic performance of companies in the life sciences sector. The importance of these intellectual property rights is even greater when considering the blockbuster drugs of big pharma companies, which often constitute a key product around which the entire value creation revolves. In this sense, patents represent the most effective form of intellectual property to protect the blockbuster product and incentivize its profitability through the monopoly rights they entail. Despite their crucial role, there is currently no stream of academic literature that uniquely identifies the valuation methodology of intellectual property assets, specifically patents, in the life sciences sector. This difficulty is due to the intangible nature of these assets, as well as the significant challenge of obtaining sufficient public information to estimate future economic benefits and key inputs for valuation, as in the case of the cost approach and the market approach.
To this end, the present work aims to identify an empirical valuation application with reference to a patent associated with a blockbuster drug in the Life Sciences sector. The work seeks to contribute to empirical valuation by identifying a valuation approach that can be applied to patents related to blockbuster drugs, in cases where they constitute the main product line of a pharmaceutical company, and at the same time in the presence of limited public information.

In this case, the object of the valuation was the American patent associated with Novo Nordisk's drug Ozempic, which in recent times has not only revolutionized the treatment of type 2 diabetes based on GLP-1 agonists but has also characterized a global social phenomenon given its potential applicability for weight loss. Considering the limited public information and the frequency of licensing agreements based on pharmaceutical patents, the Relief from Royalty Method was considered the most suitable method to authentically

represent the value of this crucial asset for Novo Nordisk. This method was also selected because it is recognized and accepted by academic literature, as well as often cited in financial and accounting valuations. To prove its application reliability, the relief from royalty method was cross-checked through the application of the rule of thumb method based on the 25% profit split, also cited by academic literature and constituting a best practice in cases of determining royalties in favor of the licensor in licensing agreements.

Therefore, the present analysis, in the first chapter, aims to describe the set of Intellectual Property Rights recognized in international legal disciplines, listing the main regional differences. The first chapter also describes the international accounting principles, and national ones for Italy, related to Intangible Assets, such as intellectual property. The second chapter describes the peculiarities of the Life Sciences sector and its prominence in recent years. Finally, after analyzing current market trends and future growth prospects for the industry, the crucial role of Intellectual Property in the Life Sciences sector is discussed.

In the third chapter, the current state of the art of valuation methods for intangible assets and intellectual property rights is described, identifying strengths and weaknesses. Finally, the last chapter presents a practical valuation case, which focuses on the American patent of the drug Ozempic, a blockbuster drug for the treatment of type 2 diabetes based on GLP-1 peptides, which has reached unprecedented sales growth levels, with greater resonance in the United States. This expansion phenomenon would not have been possible without the IP rights stemming from the related patented technology, which allowed for premium pricing as well as protection from generic competitors. Therefore, the analysis is based on the estimation of the Fair Market Value of an Intellectual Property Asset, such as the patent, related to a blockbuster drug, in order to provide a reference value that can give an appreciation of the profound value that characterizes Intellectual Property Assets within the ecosystem of business operations in the Life Sciences Industry.

Chapter I

Foundations of Intellectual Property Rights

Intellectual Property (IP) represents a holistic categorization of a set of intangible assets owned by a company or an individual; therefore, to fully understand the concept of IP, it is essential to take a step back to comprehend intangible assets and assess their impact on defining business operations and their contribution to the value of the enterprise.

1.1 Characteristics of Intangibles

The increase in international competitiveness and the widespread globalization of economies has led to a significant growth in the importance of corporate intangible assets, highlighting the issue of their valuation. This topic is not easy to address and is more complex than the valuation of tangible or financial assets. Intangibles, as highlighted by Ted Hagelin, present the following differentiating factors:

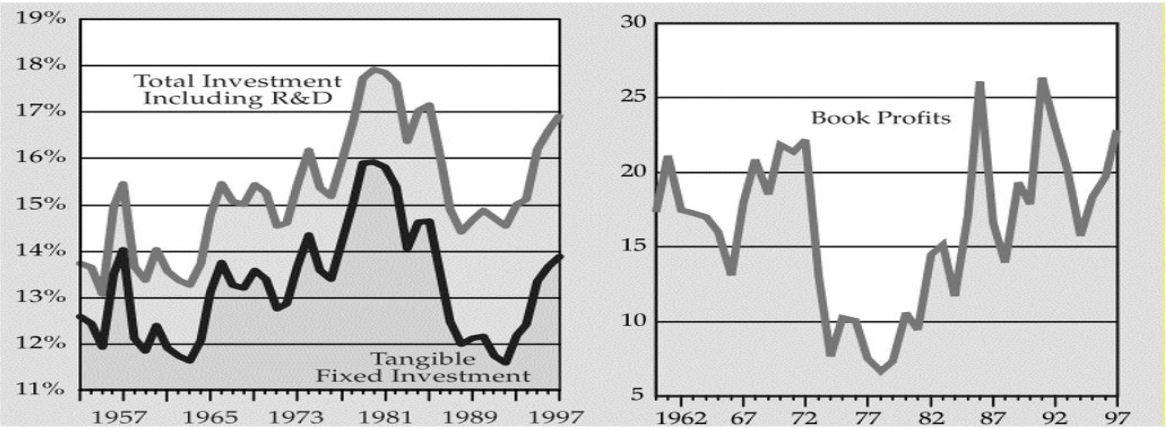
i. There is no physical public exchange market, as there is for tangible and financial assets;
ii. Intangible assets exhibit significant differences from one another, and in many cases, this difference is required by the relevant legislative framework, as in the case of Intellectual Property;
iii. The contractual conditions governing the exchange of intangibles are numerous;
iv. The conditions governing the exchange of intangible assets are generally highly confidential, making it extremely difficult to obtain information about the completed exchange. This latter aspect is almost unavoidable, as transactions related to patents or other Intellectual Property, which are based on competitive advantage, are unlikely to see the companies involved in the future disclose the contractual terms of the exchange[1].

In an increasingly complex landscape, intangible assets are playing a central role in promoting economic and business performance, representing one of the most significant sources of long-term competitive advantage. This trend is confirmed by the surge in investments in intangible assets, which arose following the Dot-com bubble, particularly as a result of the first wave of

[1]Ted Hagelin, (2002), A New Method to Value Intellectual Property.

digitalization[2]. In the United States and in 18 key countries of the European Union, from 2000 to 2013, the compound annual growth rate (CAGR) of business investments in intangible assets surpassed that of investments in physical assets:[3] Since the beginning of the new millennium, technological development and the transition from a manufacturing economy to a service-based economy have given rise to a new paradigm in the investment mix between tangible and intangible assets. In the period from 1995 to 2019, that is, during recent economic crises such as the Dot-com bubble, the 2008 global financial crisis, and the 2011 sovereign debt crisis, while non-financial companies in the United States and the 10 largest European economies reduced their Capex in tangible assets by 13%, the percentage of investments in intangible assets increased by 29%[4] , This further confirms the growing crucial role of intangible assets within the boundaries of business operations. In recent decades, the increasing emphasis on intangible assets has not been limited to companies alone but has attracted the attention of a broader range of market participants. In fact, since the early 1990s, investors have also started to recognize the importance of intangible activities' contribution to a company's value. Leonard Nakamura's groundbreaking research, "Intangibles: What Put the New in the New Economy?" highlighted a strong association between corporate investments in intangible assets and investors' perceptions of stock value. In his work, Nakamura discovered that since 1953, investments in R&D have seen a significant surge among non-financial U.S. companies, a trend that stands in stark contrast to the stable level of investments in tangible assets, as shown in Exhibit 1.1:

Exhibit 1.1 *- Gross investments as a share of GDP of non-financial companies (left) and P/E ratio based on after-accounting profits.*



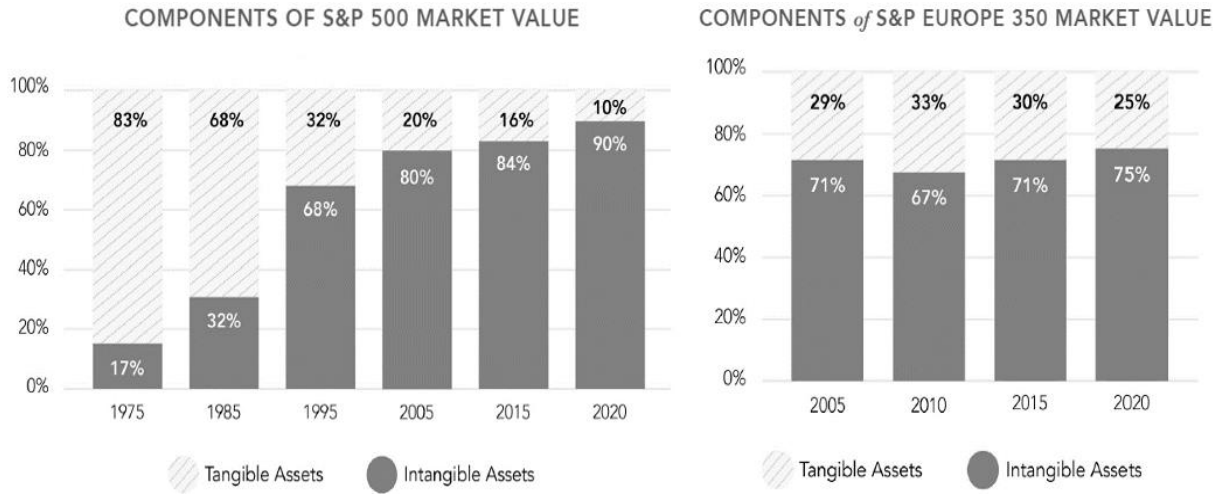
Source: L. Nakamura "Intangibles: What Put the New in the New Economy?". July 1999.

[2] Bavdaž, M., Caloghirou, Y., Dimitrić, M., & Protogerou, A. (2022)
[3] Corrado, C., Hulten, C., & Sichel, D. (2009). Intangible Capital and Economic Growth in the United States. *Review of Income and Wealth*, 55, 661-685.
[4] McKinsey Global Institute. (2021), Getting Tangible About Intangibles.

According to Nakamura, the increase in companies' intangible investments can explain the dramatic rise in U.S. stock market valuations. In fact, from 1981 to 1999, the Dow Jones Industrial Average experienced a nearly tenfold increase, outpacing the growth of reported corporate earnings, which significantly inflated the P/E multiples of all underlying sectors, as shown in Exhibit 1.2. As a result, investors began to consider intangible investments, even though they were not adequately captured by the growth in corporate earnings. Therefore, investors started to view intangible investments, even if not properly reflected by more traditional accounting measures, as a new metric to assess the company's growth potential, which strongly reinforced investors' expectations regarding the prices of underlying stocks[5].

Over the years, intangible assets have not only played a significant role in shaping market sentiment, especially in capital-intensive sectors such as telecommunications and the pharmaceutical industry, but they are also progressively becoming crucial in influencing stock market valuations. Exhibit 1.2 shows a study conducted by Ocean Tomo, which indicates the contribution of the market value of intangible assets[6] in determining stock market capitalization has seen a significant increase over the past 50 years.

Exhibit 1.2 *- Intangible Asset to Total Long Term Asset ratio of components of S&P 500 and S&P 350 Europe*



Source: Ocean Tomo, (2020) Market Value of Intangible Assets Study.

In 1975, the share of the market value of intangible assets represented only 17% of the market capitalization of the S&P 500, but from that point onward, the percentage of the market value of intangible assets increased, reaching 32% in 1985, 68% in 1995, and the 80% threshold in 2005.

[5] L. Nakamura, (July 1999) *Intangibles: What Put the New in the New Economy?*

[6] The share of the market value of intangible assets was derived by subtracting the net value of intangible assets from the market capitalization.

Since 2005, the share of the market value of intangible assets has continuously increased, reaching a remarkable figure in 2020: 90% of the market capitalization of the S&P 500 was determined by intangible assets. As shown in Figure 2, a similar trend can be observed in the 16 major developed European markets, by analyzing the S&P Europe 350 index, which includes 350 blue-chip European companies: the share of the market value of intangible assets in the market capitalization of the S&P Europe 350 has increased since 2005, contributing to 75%.[7].

It is therefore clear that intangible assets are increasingly becoming a noteworthy indicator in evaluating market value and the strategic advantage of a company, a trajectory that, based on upcoming technological advancements, will intensify in the near future. However, it should be noted that over time, numerous schools of thought have debated intangible assets, contributing theories, methodologies, and principles. Guatri and Bini highlights the debate within the Bocconi School on intangibles, sparked by two articles both published in 1989 in the journal *Finanza Marketing e Produzione*.

The first article referenced by Guatri and Bini[8] is that of G. Brugger, who, in his analysis, identifies the need for intangible assets to possess three specific components. The intangible must be: the origin of costs with deferred utility over time; transferable, meaning it can be sold to third parties (sometimes even along with other tangible and/or intangible assets); measurable in its value[9]. Brugger's analysis introduces an innovative characteristic identified in the transferability of the specific intangible asset, although this may occur in a unitary transfer with other business assets. This aspect allows assigning an independent value to specific intangible assets.

Other analysts have debated the transferability, arguing that it would limit the ability to account for intangible assets that are non-separable, such as managerial capabilities and personnel.

Guatri and Bini also refers to another thesis, according to which the specific intangible asset must possess, in addition to the always necessary requirement of measurability, one of the following two requirements:

i. It must be extractable from the company to which it belongs without compromising its continuity of life;

[7] Ocean Tomo, (December 2022) *Market Value of Intangible Assets Study*.
[8] Guatri L, Bini M, (2005), Nuovo Trattato sulla Valutazione delle Aziende, 141-160.
[9] G. Brugger, *Finanza Marketing e Produzione* – (No. 1, 1989), *The Valuation of Intangible Assets Related to Marketing and Technology*.

ii. If it remains within the company, i.e., is not extracted, it must ensure adequate profitability with historical and prospective results in line with the risk attributable to the investment in such assets[10].

A summary of the various theses under discussion is represented by Penman's thesis, which includes the following key concepts:

i. Intangibles, like any other value, can only be recognized if they are measurable with reasonable accuracy and can be supported by objective evidence;
ii. An essential condition for assigning a value to intangibles is that there must be a profit scenario for the company, and that it expresses a value higher than the cost of capital.[11]

From the perspective of their classification, intangibles can be distinguished between those acquired (for which a price has been paid) and those internally generated within the company.
Another classification method is based on the creation of homogeneous classes, leading to the distinction between marketing intangible assets and technology intangible assets.

In the first category, we find: secondary trademarks; advertising ideas; marketing strategies; product warranties; product guarantees; graphics; promotional ideas; public relations efforts; label designs; packaging designs; trademark registrations.

In the second category, we find: technology; production know-how; research and development projects; patents; trade secrets; design/styling; software; databases[12].

Ted Hagelin, in his discussion of intangible assets, identified two types of categorization:
The first type consists of a true asset, in the sense that the owner holds a legally enforceable right that allows them to appropriate the benefits derived from the intangible activity. This category includes patents, copyrights, trade secrets, and trademarks. The author refers to this type of asset as *Intellectual Property*.
The second type, unlike the first, is not a true asset because the owner does not hold rights that can be legally enforced against third parties. This category includes assembled workforce, employee training, managerial skills, and the trust placed by customers. This type of intangible asset is

[10] Ibid.
[11] Penman, *Value and Prices of Intangible Assets, An American Point of View*, paper presented at the conference at Bocconi University, Milan, October 25, 2010.
[12] Guatri L, Bini M, (2005), Nuovo Trattato sulla Valutazione delle Aziende, 141-160

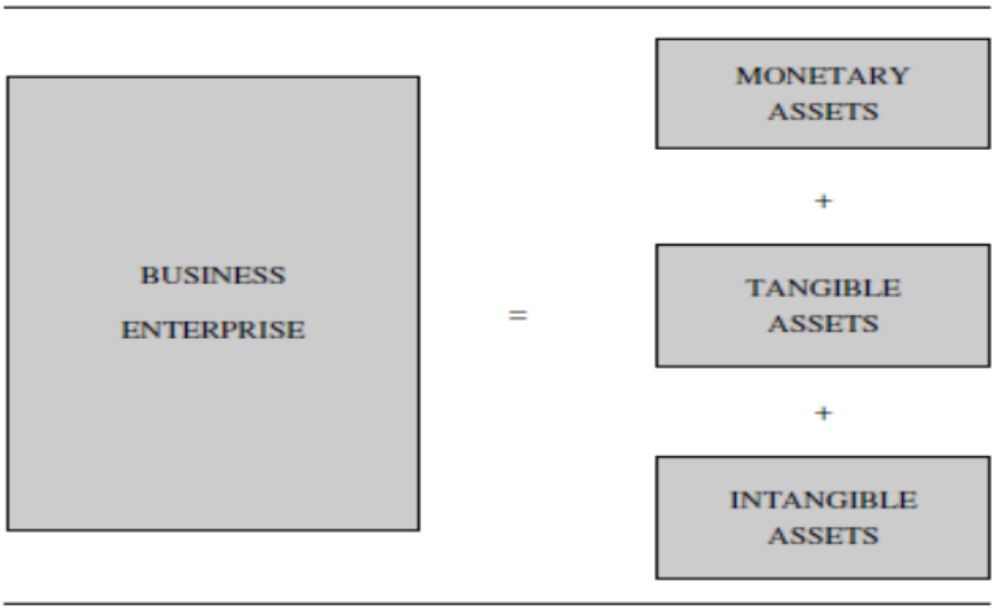
categorized by Hagelin as *Intangible Advantage*[13].

Referring to the practice below are the main intangible assets:

i. Intellectual property;
ii. Patents;
iii. Formulas;
iv. Technological Know-How;
v. Trademarks;
vi. Copyrights;
vii. Contracts;
viii. Customer Relations;
ix. Distribution Networks[14];

Furthermore, following the approach of Smith and Parr, intangibles can be identified residually as all those business elements that are neither financial assets nor tangible assets Exhibit 1.3.

Exhibit 1.3 *- Business Enterprise Value decomposed in its asset side*



Source: Parr & Smith (2005) Intellectual Property: Valuation, Exploitation, and Infringement Damages.

[13] Ted Hagelin, (2002), -A New Method to Value Intellectual Property.
[14] R. Parr, (1991), Investing in Intangible Assets, New York Wiley.

1.2 Intellectual Property Rights

In the previous paragraph, we observed that intellectual property constitutes a category of intangible business assets[15], and as we will discuss later, it benefits from legal protection. The technological and digital transformation experienced in recent decades has pushed the importance of intellectual property from an economic, legal, and political perspective. The World Intellectual Property Organization (WIPO)[16] defines intellectual property as a set of "creations of the human mind, such as inventions, literary and artistic works, designs and models, symbols, names, and images used in commerce."

Intangibles that fall under the category of intellectual property refer to the branch of law that regulates certain legal institutions within the system of legal protection for human creativity and inventiveness in the artistic, scientific, and industrial fields.[17] This system of legal protection safeguards intellectual creations by preventing third parties from using them without the owner's consent. It allows the owner to protect their creation in judicial and extrajudicial matters against third parties who use it fraudulently, and it enables the owner to economically exploit the intellectual creation, including through its definitive transfer or licensing, in exchange for a financial return. As we will see later, legal protection is aimed at Intellectual Property itself and does not protect the asset that incorporates it. For economic systems and the businesses operating within them, intellectual property rights (IPRs) are fundamental because they allow businesses to protect the economic returns derived from research and development investments. Furthermore, they help safeguard the company's reputation and provide defense against counterfeiting of their trademarks or products.

Mark A. Lemley has argued about the importance and justifications of intellectual property, providing both an ex-ante and an ex-post approach. In the ex-ante profile, the objective of intellectual property is to influence behaviors that occur before the right is granted. In the ex-post approach, arguments for justifying intellectual property focus not on incentivizing the creation of

[15] Ibid.
[16] The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations that, in accordance with the 1967 WIPO Convention, promotes and protects intellectual property worldwide, collaborating with representatives from countries and international organizations.
[17] F. Nicolli - U. Rizzo, (2012) *Intellectual Property*, in: *Dictionary of Economics and Finance*, Treccani,

new ideas, but on what happens to those ideas after they have been developed, reasoning instead on the incentives the right provides to its holder for managing already created works[18].

Concerns about intellectual property have sometimes been raised, as in the argument expressed by Michael A. Heller and Rebecca S. Eisenberg, who, in the late 1990s, discussed the risk of an excessive proliferation of fragmented and overlapping intellectual property rights that could paradoxically lead to fewer products useful for improving human health[19].

[18] Mark A. Lemley (2004) Ex Ante versus Ex Post Justifications for Intellectual Property, *University of Chicago Law Review*: Vol. 71: Iss. 1, Article 9
[19] Michael A. Heller and Rebecca S. Eisenberg, (1998) Can Patents Deter Innovation? The Anticommons in Biomedical Research- Science

1.3 Intellectual Property Assets

Intellectual Property can be subdivided into a variety of intangibles to which specific legal protection (Intellectual Property Rights) is assigned. It is by referring to the regulatory framework and the corresponding rights of protection that the identification of their main characteristics will proceed.

It should be noted that the regulatory framework is complex because individual countries sometimes adopt different rules that establish variations in the levels of protection for Intellectual Property Rights. For these reasons, at the international level, countries have sought to agree on norms for intellectual property rights in order to create a foundation for facilitating security in transactions and establishing effective support for resolving disputes in foreign jurisdictions.

One of the first international treaties to address the subject was the "Paris Convention for the Protection of Industrial Property" of 1883 – known as the "Paris Convention". Article 1 states: "The protection of industrial property covers patents for inventions, utility models, industrial designs or models, trademarks, service marks, trade names, and indications of source or appellations of origin, as well as the repression of unfair competition."[20] From the Paris Convention, the following categories of Intellectual Property are identified: Patents, Industrial Designs or Models, Trademarks, and Indications of Origin.
With the Paris Convention, the member states sought to establish that industrial property rights granted in one member state would be protected in all other member states.
This Convention, together with the Berne Convention of 1886, which addressed the protection of literary and artistic works, forms the legal foundation for the subject and has been followed by further supranational agreements.
Among these, the TRIPS Agreement - Trade-Related Aspects of Intellectual Property Rights-[21] is of significant importance. It is a multilateral agreement on intellectual property, originated by the WTO (World Trade Organization), and through it, the aspects of intellectual property rights related to trade are regulated. The TRIPS Agreement sets out the minimum standards of protection for intellectual property rights for each member country, as well as the procedures for resolving disputes regarding Intellectual Property Rights.

[20] The Paris Convention for the Protection of Industrial Property of 1883 – known as the Paris Convention. The official Italian text from 1990, published by the World Intellectual Property Organization (WIPO) headquartered in Geneva.
[21] WTO, 1994, TRIPS - Trade Related aspects of Intellectual Property Rights

The TRIPS Agreement plays a central role in the exchange and economic enhancement of knowledge and creativity, highlighting the need for a balanced international intellectual property rights system. In the agreement, intellectual property rights are identified as rights granted to individuals for the creation of their minds. These rights typically grant the creator/inventor exclusive rights to use their creation for a specific period of time.

The intellectual property rights outlined in TRIPS (Trade-Related Aspects of Intellectual Property Rights), as explained by the WTO (World Trade Organization), are divided into two main areas:

i. Copyright and related rights:

- The rights of authors of literary and artistic works are protected by copyright for a period that includes the life of the author and extends for at least 50 years after their death.
- The rights of artists, producers of phonograms (sound recordings), and broadcasting organizations are protected by copyright and related rights.

ii. Industrial Property: Industrial property can, in turn, be divided into two main areas:

- Protection of distinctive signs, which includes trademarks and geographical indications. The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, allowing them to make informed choices. Protection can last indefinitely, provided the sign continues to be distinctive.
- Other types of industrial property, whose protection aims to stimulate innovation, design, and the creation of technology. This category includes inventions (protected by patents), industrial designs, and trade secrets. The purpose is to provide protection for the results of investments in the development of new technologies, allowing for economic value and a return on financial efforts spent on research and development activities. Protection is typically granted for a limited period of time (usually 20 years in the case of patents)[22].

In addition to the WTO, the World Intellectual Property Organization (WIPO**)**, a specialized agency of the United Nations, also plays a key role in intellectual property. WIPO offers services,

[22]WTO, TRIPS - What are intellectual property rights?-

policies, information, and cooperation in the field of intellectual property and aims to develop a balanced and effective international intellectual property system that fosters innovation and creativity for the benefit of all.

Moreover, there are several other international organizations involved in intellectual property rights, including: The World Customs Organization (WCO); The United Nations Conference on Trade and Development (UNCTAD); Interpol, which handles crimes against intellectual property and counterfeiting; The Organization for Economic Co-operation and Development (OECD).

These organizations work together to promote and protect intellectual property on a global scale, supporting the development of fair and efficient international trade and innovation systems.

Focusing on Europe, the entry into force of the Treaty on the Functioning of the European Union (TFEU) in 2009 established the EU's explicit competence in intellectual property rights through Articles 114 and 118[23].

Article 114 addresses the establishment and functioning of the internal market, allowing the EU to adopt measures harmonizing national laws to ensure the smooth functioning of the internal market, including those related to intellectual property.

Article 118 grants the European Union the power to create unified rules for intellectual property, including patents and trademarks, and to establish specific procedures for the protection of these rights across all EU member states. This has enabled the creation of various intellectual property instruments, such as the European Patent and the European Union Trademark (EUTM)[24].

The instruments implemented by the European Union also incorporate the international obligations of its member states, such as those established in the Berne Convention, the Rome Convention, as well as in the TRIPS Agreement and the international treaties of WIPO (World Intellectual Property Organization).These instruments ensure that EU law aligns with global standards for intellectual property protection and enforcement, providing a framework that harmonizes national laws with international commitments, fostering innovation, and facilitating cross-border trade and cooperation.

[23] Official EN Journal of the European Union- 26.10.2012, Consolidated Version Of The Treaty On The Functioning Of The European Union
[24] Ibid.

Following the approach derived from the international regulatory framework, intellectual property can be distinguished into the following main classes:

i. Patents;
ii. Trademarks;
iii. Copyrights;
iv. Industrial Designs or Models;
v. Geographical Indications.

The topic in this discussion will primarily be directed towards the first three categories.

1.3.1 Patents

They serve the purpose of protecting an invention, product, or technical process. They make it illegal for others to make, use, resell, rent, or provide the patented object or process. However, the patent holder has the right to grant a third-party permission to use the patent by issuing a license agreement, which is an arrangement between the patent holder and the third party who wishes to use it in exchange for financial compensation.

It is a legal title granted to a technical invention if it is novel and has industrial applicability. The patent grants the holder the right to prevent others from producing, using, or selling the invention without their permission. In Europe, technical inventions can be protected by patents, which may have a national scope, as they are granted by the competent national authority, or a broader European scope if issued centrally by the European Patent Office (EPO). Since its entry into force, the EU unitary patent has provided unitary protection with equivalent effect in all participating countries. The European Patent Convention (EPC) emphasizes in Article 52 that "European patents are granted for any invention, in all fields of technology, provided that they are new, involve an inventive step, and are susceptible of industrial application." However, the EPC also provides in Articles 53 and 54 some exclusions or exceptions for the recognition of the European patent. These aspects are of particular relevance in the Life Sciences sector, where the most common IP is patents, especially in biotechnology and pharmaceuticals. In this regard, Article 53(c) highlights that "methods of treatment of the human or animal body by surgical or therapeutic intervention and diagnostic methods practiced on the human or animal body are not patentable; this provision does not apply to products, in particular substances or compositions intended for use in any of

these methods." The subsequent Article 54(4) further establishes that the patentability of any substance or composition, included in the state of the art, for use in a method referred to in Article 53(c), is not excluded, provided that its use for such a method is not included in the state of the art. Then, paragraph 5 continues: "The patentability of any substance or composition referred to in paragraph 4 for a specific use in a method referred to in Article 53(c) is also not excluded, provided that such use is not included in the state of the art"[25].

Through European legislation, companies have the possibility to protect their inventions in all EU member states. Furthermore, they can challenge or defend European unitary patents in a single legal action thanks to the Unified Patent Court, thus optimizing actions and reducing costs. The agreement establishing the Unified Patent Court stipulates that the primacy of EU law must be respected by the signatories, and that decisions of the Court of Justice of the European Union are binding for the Unified Patent Court. The court operates within 17 EU member states and consists of a first-instance court, an appeals court, and a registry. The first-instance court is decentralized, with a central division in Paris, a section in Munich, and a number of regional and local divisions throughout Europe.

What can be patented are technological innovations that have industrial applicability and qualify as new, original solutions that provide a concrete resolution to a technical problem.

An industrial invention is the solution to a technical problem that has not yet been solved. It materializes as a new method or industrial processing technique, a tool, utensil, or mechanical device, and represents an innovation compared to the "state of the art." The state of the art is the collective body of materials, documents, publications, information, and anything else made publicly available, both nationally and internationally, including all patents previously granted, prior to the filing date of the patent application.

The requirements for a patentable invention, even in the United States, must include the following characteristics:

i. *Novelty*: This exists when the invention is not already part of the state of the art (or the state of technology).

[25] EPO – European Patent Office – European Patent Convention – Part II – Substantiative Patent Law

ii. *Originality*: This allows a person skilled in the field to select, from all that is new, what stands out as significantly different from the state of the art.
iii. *Industrial applicability*: The invention must be capable of being made or used in some kind of industry, implying that it can be reproduced or applied in a practical, industrial context[26].

In terms of patentability requirements, it is important to highlight the *claims* contained in the patent application, as they define the novel elements that are intended to be protected. The claims in a patent can significantly impact its value, as they establish the scope of the patent and serve as a barrier against potential infringements by third parties. The more precisely and clearly the claims are drafted, the more effectively they can protect the invention from unauthorized use, while also increasing the potential for commercial value[27].

The patent thus offers holders a competitive advantage for the economic exploitation of their invention. However, the only certainty is provided by the legal protection lasting for 20 years, while there is no equal certainty regarding its actual applicability, which can only be subject to predictive considerations. Furthermore, it is important to consider that there is a risk associated with the patent being subjected to the "compulsory license" regime. This may occur if the competent authorities believe that the invention is not benefiting society as it should. In such a case, the business holding the patent would lose its competitive advantage, with resulting economic consequences[28].

1.3.2 Trademarks

Companies use a trademark to distinguish their products or services from those of competing businesses. Trademark rights protect product or service names, as well as the logo of a product and its packaging design. A trademark is subject to protection if the company that owns it has registered it.

All signs can potentially constitute a trademark, particularly words (including people's names), or designs, letters, numbers, colors, the shape of a product or its packaging, or even sounds, provided that these signs are suitable to: distinguish the products or services of one business from those of

[26] Expert Report of Professor Robert P. Merges-2014, In the Arbitration under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade Agreement
[27] Italian Industrial and Made in Italy Ministry - UIBM- instructions for filing applications for industrial invention or utility model patents
[28] Intellectual Property Code - D.LGS. 30/2005 - Art. 70 Compulsory license for non-implementation

others; and be represented in the register in a way that allows the competent authorities and the public to precisely and clearly determine the scope of protection granted to its owner[29].

In the European Union, the legal framework for trademarks is based on a four-tier system for their registration, which, however, coexists with national trademark systems that are harmonized by the EU Trademarks Directive (EU Directive 2015/2436)[30]. In addition to the national scope, there are other avenues for trademark protection within the EU, particularly with the European Union Trademark (EUTM) introduced in 1994, which is issued by the European Union Intellectual Property Office (EUIPO). EU Regulation 2017/1001 specifically addresses the European Union Trademark, codifying and replacing all previous EU regulations on the subject of EU trademarks, providing greater legal clarity[31]. The European Union Trademark has a unitary character, and the responsibility for its management has been entrusted to the EUIPO. Regarding designs and models, Directive 98/71/EC applies[32]. It is also important to highlight Decision 2006/954/EC, which approves the European Community's accession to the Geneva Act of the Hague Agreement concerning the international registration of industrial designs, adopted in Geneva on July 2, 1999, and Council Regulation No. 1891/2006, both dated December 18, 2006, which connected the Union's design registration system to the international registration system for industrial designs of WIPO (World Intellectual Property Organization)[33].

Based on the elements that make it up, a trademark can be classified as follows:

i. *Word mark*, consisting solely of words;
ii. *Figurative mark*, represented by a figure or a reproduction of real or imaginary objects;
iii. *Shape or three-dimensional mark*, consisting of a three-dimensional shape that may include containers, packaging, the product itself, or their appearance;
iv. *Sound mark*, represented exclusively by a sound or a combination of sounds;
v. *Motion mark*, characterized by a change in position of the elements of the trademark;
vi. *Multimedia mark*, consisting of a combination of image and sound;
vii. Pattern mark**;**

[29] Official Gazette of the European Union (December 2015) EU Directive 2015/2436, on the approximation of the laws of the Member States relating to trademarks
[30] Ibid.
[31] Official Gazette of the European Union, (June 2017), EU Regulation 2017/1001 of the European Parliament on the European Union Trademark.
[32] Official Gazette of the European Union (June 2017), EU Regulation 2017/1001 of the European Parliament on the European Union Trademark.
[33] Official Gazette of the European Union (December 2016)

viii. Position mark**;**

ix. *Holographic mark*, consisting of elements with holographic characteristics;

For the purpose of trademark registration, the Italian regulations establish that one of the signs listed above must meet the following requirements:

i. *Novelty*: The trademark must be new; it cannot be identical or similar to trademarks already filed for identical or related products or services. Additionally, it cannot be identical or similar to signs that have become common in everyday language or trade practices, or to signs already known, such as company names, trade names, business names, signs, or domain names (Article 12 of the Industrial Property Code - CPI).

ii. *Distinctiveness*: Signs that lack distinctive character cannot be registered as trademarks (Article 13 of the CPI).

iii. *Legality*: The trademark cannot violate the law (Article 14 of the CPI)[34].

Unlike patents, a trademark is an intellectual property right with, in theory, an infinite time limit, meaning that the exclusive right is granted for ten years but can be renewed for the same period as many times as desired. In common language, the terms "mark" and "brand" are often used to refer to a trademark. This is an error, as "mark" has a broader meaning than trademark. The term "mark" encompasses a range of activities primarily related to marketing carried out by a company for commercial purposes, including the trademark itself. In contrast, a trademark has a more specific definition based on legal regulations.

1.3.3 Copyrights

Copyright protects intellectual works in literature, science, and art, including books and articles, films, paintings, music, games, photographs, and software. Copyright arises automatically with the creation of the work and, therefore, does not require any formalities or registration[35]. The expressive form is protected when it reaches a sufficient level of complexity and creativity and must also reflect the author's choice in how the content of the work is expressed.

[34] Code of Industrial Property (CPI), Issued by Legislative Decree No. 30 of February 10, 2005

[35] Italian Ministry of Culture and Tourism, Copyright Law (Law No. 633 of April 22, 1941, and subsequent amendments and integrations)

Copyright ensures that authors, composers, directors, and other artists receive compensation for their works and that these works are protected. The distribution of content protected by copyright and related rights is therefore subject to the granting of licenses by the various rights holders. Rights holders often entrust these rights to collective management organizations, which manage them on their behalf.

The law outlines two types of copyright: economic exploitation rights of the work and the moral rights of the author[36].

The first rights are the exclusive rights granted to the author, which allow them to economically exploit their work, authorize any use of it, and receive the related compensation. These rights can be distinguished as follows**:**

i. Right of performance, representation, or public recitation
ii. Right to reproduce the work in copies;
iii. Right of communication to the public;
iv. Right of publication;
v. Right of transcription from oral to written *form;*
vi. *Right* of adaptation and modification of the work;
vii. Right of rental and lending.

These rights are independent of each other, meaning they can be exercised either separately or collectively. They may apply to the entire creation or to part of it. The author may waive or assign these rights to third parties. However, they are exercisable within a time limit, which is the life of the author plus an additional 70 years[37] after their death. After this period, the work enters the public domain and can be used freely.

Moral rights are rights aimed at protecting the work and defending the personality of the author. These rights allow the author to decide if and when to publish the work, to claim authorship, to oppose any distortion or act that could harm the work, and to withdraw it from circulation.

[36] Ibid.
[37] Official Gazette of the European Union, (October 2011), Directive 2011/77/EU, which amends Directive 2006/116/EC concerning the duration of protection of copyright and related rights.

Unlike economic rights, moral rights are inalienable, non-prescriptive, and cannot be waived. They are independent of property rights and can be exercised even if the economic rights are transferred to third parties. Moreover, unlike economic rights, moral rights do not have a time limit, and after the author's death, they can be exercised by their heirs[38].

The introduction of digital technologies has significantly changed the way creative content is produced, distributed, and accessed. EU legislation on copyright is structured through directives and regulations that harmonize the main copyright laws. The regulations at the Union level help reduce national disparities, ensure the necessary level of protection to stimulate creativity and investment in it, promote cultural diversity, and, finally, facilitate access to digital content and services for consumers and businesses across the entire single market.

With Directive 91/250/EEC, Member States were required to protect computer programs through copyright, which are therefore considered literary works[39]. Directive 96/9/EC (the Database Directive) was introduced to provide legal protection for databases, defined as "a collection of works, data, or other independent elements systematically or methodically arranged and individually accessible by electronic means or otherwise." The directive provides protection for databases through copyright for the intellectual creation, and additional protection based on the right to safeguard the investment in obtaining, verifying, and presenting the content[40].

On May 30, 2022, the European Parliament and the Council adopted the Data Governance Regulation, which introduces mechanisms aimed at facilitating the reuse of certain categories of protected public sector data, strengthening trust in data intermediation services, and promoting data altruism across the EU[41].

After explaining the main categories of intellectual property, we now turn our attention to the national regulatory framework, which is centered around the Industrial Property Code (CPI)**,** issued by Legislative Decree No. 30 of February 10, 2005[42]. The CPI introduced a comprehensive and structured framework for the protection and enhancement of intellectual property rights,

[38] Ibid.
[39] Official Gazette of the European Union (May 1991), Directive 91/250/EEC of the Council, concerning the legal protection of computer programs.
[40] Official Gazette of the European Union (March 1996), Directive 96/9/EC of the European Parliament and of the Council, concerning the legal protection of databases
[41] Official Gazette of the European Union (May 2022) Regulation (EU) 2022/868 of the European Parliament and of the Council on European Data Governance.
[42] Code of Industrial Property (CPI), emanato con Decreto Legislativo 10 febbraio 2005, n. 30

intervening in terms of reorganization and consolidating over 40 regulations represented by laws and provisions, many of which stemmed from the adaptation of Italian laws to EU regulations and the provisions of international conventions to which Italy has adhered. The single text on industrial property thus resulted in a significant simplification. However, just one month after its publication, a first modification was made with Article 1-quater of the decree-law No. 35 of March 14, 2005, which established the High Commissioner for the fight against counterfeiting and consequently abolished the National Anti-Counterfeiting Committee.

Subsequently, further regulatory measures were enacted for alignment, such as:

i. Legislative Decree No. 140 of March 16, 2006, which adjusted the Code to Directive 2004/48/EC on the enforcement of intellectual property rights[43];
ii. The Decree-Law No. 10/2007 (Provisions aimed at implementing EU and international obligations) amended the Code by extending the duration of copyright protection for designs and models from twenty-five years to seventy years.
iii. Law No. 102/2023 is part of the reform outlined in the National Recovery and Resilience Plan (PNRR) and aims to achieve two fundamental objectives: strengthening the competitiveness of the national system and the protection of industrial property; simplifying administrative processes and digitizing procedures[44].

Law No. 102/2023 specifically intervened on the ownership regime of inventions obtained within the framework of university research activities. Until Law 102/2023, the regulation was based on the "professor's privilege," meaning the attribution of industrial property rights to university researchers for patentable inventions made during research activities. There were multiple calls for reform, as activities related to the transfer of such inventions were considered essential in the processes of exploiting innovation.

With the introduction of Law No. 102/2023, Article 65 of the Industrial Property Code (CPI) grants universities and research institutions ownership of the rights related to inventions made by researchers, provided that the inventions were created within the context of an employment or work relationship, even if of a temporary nature, with the university.

[43] Legislative Decree No. 140 of March 16, 2006, "Implementation of Directive 2004/48/EC on the enforcement of intellectual property rights."
[44] Italian Official Gazette (August 2023) N 184, Law 24 July 2023, n. 102

Among the entities included within the scope of the regulation are public and private universities, public research institutions, scientific hospitals and care institutes ("IRCCS"), and other non-profit research and technical-scientific promotion organizations, or those operating under agreements between such entities. Article 65 of the Industrial Property Code (CPI) aligns the treatment of university and research institution inventions with the provisions set out in Article 64 of the CPI for the private sector, which grants the employer, under certain conditions, the rights to inventions made by employees within the framework of an employment relationship.

Through the reform of Article 65 of the Industrial Property Code (CPI), it is expected to alleviate, if not eliminate, the difficulties arising from the previous regulatory framework for the exploitation of inventions. In the past, researchers who held the rights to their inventions often lacked the means to properly protect and maximize the potential of these inventions derived from research activities. The new regulations should make the transfer of new technologies to the productive system more efficient and faster. Universities and research institutions, as patent holders, will now be able to compete on equal footing with private companies in the market and invest in innovations that show promising prospects for significant results[45].

[45] Code Industrial Property (CPI), enacted by Legislative Decree No. 30 of February 10, 2005.

1.4. Accounting for intangible assets

Given the growing importance of intangible assets in shaping market sentiment and the market capitalization of companies, it is crucial to adhere to a solid accounting system capable of accurately recognizing them in financial statements, which are the most important source of information guiding all stakeholders in their financial decision-making process. However, due to the intangible nature of these assets, accounting for them effectively and comprehensively poses a formidable challenge; as a result, numerous experts have differing opinions on the principles to adopt for their recognition and measurement.

In the early 2000s, with the introduction of the American accounting principles SFAS 141 and SFAS 142, guidelines were established for the accounting treatment of specific intangible assets (distinct from goodwill), emphasizing two distinguishing characteristics: the separability of the intangible asset and its derivation from contractual rights or other rights. The two principles address the accounting for intangible assets acquired individually or as part of a group of other assets at the time of acquisition. Additionally, they cover the accounting for events that occur after the assets are recorded in the financial statements[46]. Specifically, regarding events occurring after the initial recognition, SFAS 142 introduces the criterion according to which goodwill and intangible assets with an indefinite useful life will not be amortized but will instead be subject to an annual impairment test to determine any potential reduction in value. Intangible assets with a defined useful life will continue to be amortized over their useful life, as with other assets. However, these principles do not address the accounting treatment of internally developed intangible assets, for which the guidelines previously issued under APB 17, "Intangible Assets" (1970), remain unchanged[47].

Referring to the Italian accounting system, the OIC (Italian GAAP) with Accounting Principle 24, issued in December 2016 and later updated with amendments on December 29, 2017, regulated the criteria for the recognition, classification, and measurement of intangible assets, as well as the information to be presented in the notes to the financial statements[48]. The OIC 24 principle applies to companies that prepare their financial statements based on the provisions of the Civil Code. Specifically, the provisions of the Civil Code referring to the preparation of the accounting

[46] FASB- Financial Accounting Standards Board, (June 2001), SFAS n.141 Business Combinations, SFAS 142. Goodwill and Other Intangible Assets.
[47] FASB- Financial Accounting Standards Board, APB 17 Intangible Assets agosto1970.
[48] Fondazione OIC – Accounting Principles No. 24 – January 2015.

principle are those outlined in the chapter concerning intangible assets in the civil law legislation[49]. These are typically intangible assets, consisting of costs that do not exhaust their utility in a single period and provide economic benefits over a period of multiple years.

Article 2424 of the Italian Civil Code provides that intangible asset, under the "BI" section of the balance sheet, should be listed under the assets of the balance sheet according to the following classification:

i. Start-up and expansion costs;
ii. Development costs;
iii. Industrial patents and rights to use intellectual works;
iv. Concessions, licenses, trademarks, and similar rights;
v. Goodwill;
vi. Work in progress and advances[50].

Intangible assets are, therefore, non-monetary assets, individually identifiable, lacking physical substance, and are, in most cases, represented by legally protected rights. Intellectual Property is, therefore, generally accounted for as intangible assets. In this regard, OIC 24 highlights that an intangible asset is considered individually identifiable when:

i. It is separable, meaning it can be separated or disassociated from the company and, therefore, can be sold, transferred, licensed, rented, or exchanged;
ii. It originates from contractual rights or other legal rights. These include industrial patents, rights to use intellectual works, concessions, licenses, trademarks, and other similar rights.

The BI3 item of the Italian GAAP balance sheet, "industrial patent rights and rights to use intellectual works," may include:

i. Costs for both internal production and external acquisition of rights to use intellectual works;
ii. Costs for the acquisition or production of patents for utility models and ornamental models and designs;
iii. Costs for licensing rights for patents;

[49] Di Maio A., Civil Code Section IX Balance Sheet art. 2423 e 2435, Giuffrè Editions
[50] Ibid.

iv. Costs related to the acquisition or licensing of application software, both for fixed-term and indefinite-term licenses;
v. Costs incurred for the internal production of application software protected under copyright law;
vi. Know-how costs, whether incurred for internal production or purchased from third parties, when legally protected;
vii. Industrial patent rights and rights to use intellectual works may be transferred through a license of use[51].

The BI4 item of the Italian GAAP balance sheet, "concessions, licenses, trademarks, and similar rights," may include:

i. Costs for obtaining concessions on assets owned by granting entities (exclusive exploitation of public assets, such as state-owned land);
ii. Costs for obtaining concessions for activities of granting entities (regulated management of certain public services, such as highways, transportation, parking, etc.);
iii. Costs for retail trade licenses;
iv. Know-how costs for non-patented technology;
v. Costs for the purchase, internal production, and licensing rights for trademarks[52].

In the case where the intangible asset is generated internally, the production cost includes all costs directly attributable to the intangible asset. It may also include other costs, such as the portion reasonably attributable to the asset, for the production period and until the intangible asset is ready for use. Using the same criteria, costs related to the financing of the production, whether internal or outsourced, may also be included, following the same methods provided by OIC accounting principle 16.[53] The OIC 24 principle highlights, however, that the costs of basic research carried out by the company, which do not have a clearly defined purpose, must be charged to the income statement for the period and cannot be capitalized. Capitalization is, in fact, allowed for costs related to applied or targeted research for a specific product or process that are technically feasible, or for development costs, or for costs related to the application of research results. In order to

[51] OIC Foundation – Accounting Principles No. 24 – January.
[52] Ibid.
[53] OIC Foundation – Accounting Principles No. 16, Tangible Fixed Assets, December 2016, updated in December 2017.

capitalize these costs, it is also required that the company has prospects for recovering them through the revenues it expects to generate from the product or process.

The national accounting system referenced by OIC 24, unlike American accounting principles, allows for the capitalization of internally generated intangible assets in the balance sheet.

The cost of intangible assets must be systematically amortized in each fiscal year in relation to their residual useful life[54]. The amortization expense allocated to each period must reflect the allocation of the cost over the entire useful life of the intangible asset. Amortization begins when the intangible asset is available and ready for use.

The residual value of an intangible asset is assumed to be zero, unless: there is a commitment by a third party to purchase the intangible asset at the end of its useful life; or there is evidence of an active market for the asset, allowing an objective value to be derived that facilitates an accurate estimate of the realizable value from the asset's disposal at the end of its useful life. At each balance sheet date, the company must assess the presence of any indicators of impairment related to intangible assets. If such indicators exist, the company must estimate the recoverable amount of the asset and recognize an impairment loss. The topic of impairments is addressed by OIC through the accounting principle 9 "Impairments for permanent losses in value of tangible and intangible assets".[55]

Intangible assets can be subject to revaluation only in cases where the law provides for or allows it. Discretionary or voluntary revaluations are not permitted. The maximum limit for the revaluation of an intangible asset is its recoverable amount, and it cannot exceed this value in any case.

If the revalued amount of an intangible asset exceeds its recoverable amount in subsequent periods, the revalued amount must be impaired, with the recognition of the permanent loss in the income statement (according to the guidelines provided in OIC Principle 9), unless the law specifies otherwise.

Revaluation of an intangible asset does not alter its estimated remaining useful life, which is independent of the asset's economic value. The amortization of the revalued intangible asset

[54] *Di Maio A.,* Civil Code Section IX Balance Sheet *,* art. 2426 ,Giuffrè edition.
[55] Fondazione OIC – Accounting Principles.

continues to be determined consistently with the criteria previously applied, without changing the remaining useful life.

When an intangible asset is sold, the corresponding accounting entry must be eliminated from the balance sheet, in exchange for the consideration received, at the net carrying amount of the disposed asset. This means the asset's net book value, which includes accumulated amortization up to the date of sale, also incorporating the amortization for the portion of the last financial year in which the asset was used. Any difference between the net book value and the sale consideration, which represents ei

According to the International Financial Reporting Standards (IFRS®), intangible assets are defined within the scope of IAS 38, according to which an intangible asset is "an identifiable, non-monetary asset without physical substance."."[56] The Conceptual Framework for Financial Reporting, provided by the IFRS, establishes the definition of an asset, which is "a present economic resource controlled by the entity as a result of past events"[57] and from which future economic benefits are expected[58].

Therefore, according to the IASB, for an asset to be classified as an intangible asset, three main criteria must be met: identifiability, control, and future economic benefits arising from that control.

The most debated criterion is undoubtedly that of identifiability, which implies that the asset must be separable or arise from legal or contractual rights (the latter can also be separable, but this is not a fundamental requirement). Separable intangible assets are those that can be distinguished from the entity as a whole and transferred independently, meaning that these assets can be acquired without acquiring the entire business. An intangible asset arising from legal or contractual rights, regardless of its transferability, means that as long as the value of the intangible asset and its identification are protected by a legal right or sealed by a contractual relationship, the asset can be identified as an intangible asset. For an intangible asset to be recognized on the balance sheet, it must meet two requirements: future economic benefits attributable to the asset will flow to the entity, and the cost of the asset can be reliably measured[59]. For recognition purposes, acquired intangible assets fall within the scope of recognition and are initially recorded at cost. However,

[56] IFRS IAS 38.
[57] Conceptual framework for financial disclosure based on IFRS.
[58] IAS 38.
[59] Ibid.

the treatment of internally generated intangible assets remains a topic of controversy among academics and industry professionals: in general, aside from specific cases such as development costs, software development, patentable inventions, and works subject to copyright, internally generated assets cannot be capitalized[60].

This is mainly due to the difficulty in accounting for the actual economic benefits derived from the intangible asset and the specific costs attributable to the underlying activity.

The definition proposed by the IASB seeks to emphasize the legal form and contractual rights to provide a solution to the dilemma of recognizing intangible assets, although the recognition criteria established by IAS 38 still raise doubts among scholars, as they are characterized by a significant limitation: the recognition criteria primarily apply to non-monetary intangible assets that have been "acquired" and for which the entity has paid a price. This price may not be specific to individual assets, and it can be direct or indirect, but the essential condition is that the price has been negotiated between independent parties[61].

Based on this last paradigm, the sale of a business unit within a group or the merger between the parent company and a subsidiary, or more generally when the two entities involved are related parties, the underlying price cannot be considered reliably measurable[62]. Therefore, the preliminary condition for the recognition of the intangible asset is no longer met. Over the years, other scholars have sought to provide a more comprehensive definition of intangible assets in order to guide analysts in their recognition and valuation, such as the theory provided by Stephen H. Penman. Penman acknowledges that several high-value intangible assets (such as intellectual capital and knowledge assets) are not reported on the balance sheet; however, he provides a rational framework to include a spectrum of intangible assets. The framework revolves around the criterion of reliability, which requires that "assets and liabilities are recognized only if they can be measured with reasonable precision and supported by objective evidence, free from opinions and biases." [63]Therefore, as long as the asset meets the reliability criterion, meaning that the asset can be measured reliably, the intangible asset can be recognized. The reliability criterion proposed is also closely linked to the fundamental requirement for the measurement of an intangible asset: the underlying asset must generate returns that exceed the required rate of return for the book value of

[60] ACCA, Association of Chartered Certified Accountants.
[61] Guatri L, Bini M, (2005), Nuovo Trattato sulla Valutazione delle Aziende, 141-160.
[62] Ibid.
[63] H. Penman, (2003) Value and Prices of Intangible Assets: A Fundamental Perspective.

the company's assets. For intangible assets to have value, they must be justified by their contribution to the company's earnings, creating additional value over and above the book value of the assets reported on the balance sheet.[64] In any case, the academic and professional community is still debating the accounting principles related to intangible assets. Not by chance, the IASB has scheduled for 2024, together with proposing accounting entities, a new research project, the "Third Agenda Consultation" for IAS 38. The research project was established because the project was first defined in 2024. The research project was initiated due to widespread concerns raised by stakeholders regarding the accounting treatment of internally generated intangible assets[65], meaning that further improvements and changes will need to be made to establish an accounting system that is generally validated.

The current approach to assess whether an internally generated intangible asset meets the necessary conditions for recognition in the financial statements—which, as a reminder, requires that the intangible asset will generate future economic benefits for the entity and that the cost of the asset can be reliably measured—requires reference to the process of creating the intangible asset by verifying the existence of its distinction into:

i. Research phase;

ii. and a development phase

These phases must be distinct and distinguishable. [66] It should be noted that international accounting standards differ from national standards because, in the latter, the stages of the process are divided into three phases: basic research, applied research, and development.

Under IFRS, if a company is unable to distinguish the two phases mentioned above in relation to an internal project for the creation of an intangible asset, all costs incurred for the project must be accounted for as if they were incurred exclusively in the research phase. Therefore, the intangible asset cannot be recognized.

An intangible asset arising from the Development Phase is recognized only if the company can demonstrate the following:

[64] Ibid.
[65] Deloitte IAS Plus, (April 24, 2024) *IASB Launches Research Project on Intangibles*.
[66] IFRS 38.

i. The technical feasibility of completing the intangible asset so that it will be available for use or sale.
ii. The ability to reliably measure the cost attributable to the intangible asset during its development.
iii. The availability of adequate technical, financial, and other resources to complete the development and use or sell the intangible asset, for example through cost accounting systems.
iv. The intention to complete the intangible asset for use or sale.
v. The ability to use or sell the intangible asset.
vi. How the intangible asset will generate probable future economic benefits, applying the principles of IAS 36. Additionally, the company must demonstrate the existence of a market for the product of the intangible asset or for the intangible asset itself, or, if it is to be used for internal purposes, the utility of such intangible asset[67].

The cost of an internally generated intangible asset is represented by the sum of the expenses incurred from the date when the intangible asset first meets the conditions for recognition in the financial statements. It includes all expenses that can be directly attributed or allocated based on a reasonable and consistent criterion to create, produce, and prepare the asset for its intended use.

After initial recognition, the intangible asset must be recorded in the company's balance sheet, with the choice between the cost model and the revaluation model. If the company chooses the first model, the intangible asset is recorded at cost less accumulated amortization and any accumulated impairment losses. If the company adopts the revaluation model, the intangible asset must be recorded at its fair value as of the revaluation date, less any accumulated amortization and any accumulated impairment losses. The IFRS principle establishes that the fair value must be measured with reference to an active market. The company adopting the revaluation model must carry out revaluations regularly so that the carrying amount does not differ from the fair value at the balance sheet date[68].

[67] Ibid.
[68] Ibid.

Chapter II

The Life Sciences Sector: the role played by Intellectual Property Rights

2.1 The Emergence of the Life Sciences Sector

Characterized by a strong focus on innovation, the life sciences industry stands as a strategic cornerstone of global economy, constituting a crucial primer for development in healthcare, agriculture, and sustainability. Life sciences represent a holistic domain which encompasses a broad spectrum of industries, including biotechnology, pharmaceuticals, medical devices, genetics, bioinformatics, nutraceuticals, cosmeceuticals, food processing, and all the other products dedicated to improving the quality of human lives.

The emergence of the life sciences industry stems from the evolution of the genetics field, which has opened the door to substantial business opportunities. The sequencing of human genome, which traces its own origins in the early 1990s with the *Human Genome Project*[69], suddenly developed a common language[70] among all the different companies operating with living things and organic compounds. The understanding of this set of rules, allowed companies to explore the commercial implications of mapping the genes of human DNA, which led these undertakings to share a common business model, thus dissolving the boundaries between industries that were once considered distinct. The borders separating sectors such as agriculture, chemicals, pharmaceuticals, and healthcare are now becoming increasingly fluid, as they converge under the common umbrella of life science.

This «*great convergence*» ultimately mirrors the transformation experienced during the digital revolution, as separated industries like publishing, telecommunications, and computing became interwoven through the shared language of the binary code.[71]The parallelism becomes even clearer in considering the close interdependence between natural biology and pharmaceuticals. It is no coincidence that several large pharmaceutical companies such as Bayer have expanded their business model by acquiring companies active in agrochemicals, such as Monsanto in 2016,

[69] The Human Genome Project completed in 2003, successfully mapped the entire human genome, identifying some 20,000-25,000 genes and sequencing the 3 billion base pairs of DNA.
[70] The genetic code, defined through the studies of Human DNA, is the set of rules used by living cells to translate information encoded within genetic material.
[71] Harvard Business Review. "Transforming Life, Transforming Business: The Life-Science Revolution." HBR, March 2000.

thereby leveraging common biotechnology foundations to develop high-yielding and disease-resistant crops, and at the same time innovative drugs.

Further cross-sectoral connections become apparent when taking into account the crucial role played by animal genomics in drug testing and preclinical research, indeed, through the study of animal genetics, researchers can understand what impacts certain drugs and vaccines may have on animals and by extension on humans, the latest example is constituted by SARS-CoV-2 vaccine, whose efficacy have been previously tested on mouse, golden hamster, ferret, NHPs models.[72] Furthermore, animal genomics has been closely related to the pharmaceutical industry in order to produce animal-derived drugs, examples of common use are Heparin Sodium, derived from porcine mucous, or live varicella vaccine, derived from hydrolyzed porcine gelatin. As Life Sciences continue to evolve, the intersection of genetic engineering with other fields like information technology is already evident, as digital technologies are one of the main epicenters around which biotechnological research rotates.

The convergence of the industries underlying the life sciences not only suggests the presence of a common business model based on genetic engineering but also the presence of multiple forms of cross-industry cooperation. From the latter have emerged several industrial players such as Contract Development and Manufacturing Organizations (*CMDOs)* who play critical roles in supporting the pharmaceutical, biotech and medical devices industries. Contract research Organizations (CROs) and Contract Manufacturing Organizations (CMOs), such as IQVIA and Parexel, support companies' efforts to research, test, refine, manufacture and market drug products and medical devices.

In this new ecosystem, biotechnology and pharma industries thrived, becoming deeply interconnected, standing as the main drivers of the Life Sciences industry. Under the presence of several opportunities arising from the exploitation of recombinant DNA, large pharmaceutical companies in the early 1990s reacted by forming alliances with smaller biotech firms, leveraging their technical expertise, patents, and niche technologies, thereby expanding their R&D networks previously characterized by scientific institutes and academia. In turn, biotech firms received financial support and access to large pharmaceutical companies' robust manufacturing and marketing capabilities. To this purpose, big pharma companies have undertaken two distinct

[72] Mastrolia, S. A., et al. (2021). The life sciences revolution in 2030: How genomics, AI, and biotechnology will shape healthcare. PMC.

strategies. In fact, several pharmaceutical companies have focused on obtaining specialized expertise in specific areas of biotechnology. An example of this is Eli Lilly, which used contract manufacturing to draw on knowledge of recombinant DNA for the development of its insulin. On the other hand, other big pharma acquired basic research capabilities and then used them in the various areas of drug discovery, as in this case Merck, which leveraged alliances for general capabilities in technology to develop small organic molecule as drugs.[73] Biotechnology is closely intertwined with the pharmaceutical industry, particularly in the processes of drug discovery and development process, which ultimately define the fundamental risks and rewards inherent in the industry's core business model. Given the convergence of the fields that make up the life sciences industry and given the latter's trend toward increasingly cross-industry expansion, it seems clear that the latter should not be understood as separate entities but as an integral part of a holistic concept. However, it may be useful to define a decompartmentalization of the set of scientific disciplines that characterize this industry. Exhibit 2.1 provides a brief description of the major scientific disciplines embedded in the Life Sciences sector.

Exhibit 2.1 *- Branches of Life Sciences.*

Scientific Discipline	Definition
Biology	Study of physiological processess, including molecular biology, biochemistry,and cell biology
Cell Biology	Study of physiological processes and mechanisms that allow life processes to operate at the molecular level, including cellular structure, division, energy exchange, signaling pathways and more
Biochemistry	Study of chemical interactions within a living organism
Environmental Science	Study of enivironmental issues using a combination of physisics, geology, chemistry and geography
Neuroscience	Study of the structure, development, and function in an organism of the nervous system
Genetics	Study of genes and how each gene is passed from one generation to another
Genomics	Study of the mechanistic expression of a gene and its interactions with other genes and the environment
Proteomics	Study of the attributes of protein to identify specific targets for the treatment of a particular disease
Other Branches	Ecology; Botany; Zoology; Microbiology; Entomology; Epidemiology; Paleontolgy; Marine Biology; Food Sciences

Sources: Oxford Dictionary of Science

[73] Galambos L., Galambos, L., & Sturchio, J. L. (1998). Pharmaceutical Firms and the Transition to Biotechnology: A Study in Strategic Innovation. Business History Review, 72(2), 250-278.

The life sciences industry thus encompasses a complex group of scientific disciplines, united by the same business model, which focuses on research, development, production, and marketing of products and services that benefit human lives and every living thing. Given the industry convergence of the last decades, and the future trajectory of the industry, which will imply an increasing presence of information technologies and artificial intelligence across the research and production stages, the life science sector should be regarded as a single, comprehensive, multidisciplinary entity, instead of a simple aggregate of separate industries. Traditionally, the life sciences industry is broken down in three main industries: pharmaceuticals, biotechnologies, and medical devices.

Biotechnology industry combines the study of cells and cell-based molecules to derive technologies in order to address biological problems and improve the well-being of other life forms, thus being defined also as «technology of hope».[74] The biotechnology sector exploits biological agents and microorganisms to produce pharmaceuticals, foods, biochemicals and various derivatives utilized for various applications in nanotechnology, cloning, gene therapy, embryonic stem cells, biofuels and biobanks[75]. On the other hand, the pharmaceutical industry is historically interconnected with the development and synthetization of drug products stemming from chemicals. Biotechnology and pharmaceutical industries are becoming increasingly overlapping, especially considering the modern drug development process where biotechnological companies are at the forefront of the target validation and lead optimization phases, and even with cell-based molecules employed in the drug engineering process: henceforth, several pharmaceutical firms are merging in the form of «biopharmaceutical companies».[76]
In the midst of these industries CROs and AMCs stand as vital entities for biomedical research. CROs are contract vendors that provide support across the stages of product development from target validation to phase III of clinical trials, reducing costs and increasing the speed of the time-to-market of new drugs. Academic Medical Centers (AMCs) in parallel offer advanced biomedical research supporting industries and public health organizations.[77]

[74] Gupta, V., Sengupta, M., Prakash, J., & Tripathy, B. C. 2016. An Introduction to Biotechnology. Basic and Applied Aspects of Biotechnology, 1–21.
[75] Chekol C and Gebreyohannes M. 2018. Application and Current Trends of Biotechnology: a Brief Review.Austin J Biotechnol Bioeng. 5(1): 1088.
[76] Stanton K. 2022. Biotech vs pharma: Differences and similarities. Qualio – QMS for Life Sciences.
[77] Dayal S. Heath J. What Are Life Sciences? Leica Biosystems.

In the presence of this new paradigm, Information Technologies play a crucial role in the drug design process, thereby creating an interdisciplinary field between IT, Pharmaceuticals and Biotechnologies, enabling researchers to analyze large genomic datasets. IT have been increasingly exploited in the simulation of complex biological processes and modeling drug interactions before physical testing, thus transitioning from «*in vitro*» research (laboratory-based), to «*in silico*» research (computer-simulated). With the advent of Artificial Intelligence, *in silico* research will stand as a cornerstone of personalized medicine and modern drug discovery: AI can further improve the computation-aided drug design process, thereby increasing the probability of success for selecting the first-in-class drug[78]. IT companies will play a crucial role in the Life Sciences by providing powerful computational tools, cloud platforms, and machine learning algorithms, making even more fluid the boundaries among the industry involved in the life sciences sector.

[78] Mak KK, Pichika MR. Artificial intelligence in drug development: present status and future prospects. Drug Discov Today 2019; 24: 773-80.

2.2 Market Trends in the Life Sciences Sector

In recent the years, the life sciences industry has assumed a crucial role in the global economy catalyzing investments and scientific progress, especially in the wake of the Covid pandemic emergency. The healthcare crisis that has vertically affected all countries around the world has highlighted the strategic importance of solutions in pharmaceuticals, biotechnology, and diagnostics industries, creating fertile ground for growths in market size and business performance and for the integration of new technologies with the intent spurring further innovation.
From the pandemic outbreak the Life Sciences Sector experienced a rapid growth, fostered by regulatory support, cross-firm cooperation, M&A activity, technology advancements, and extensive R&D investments, thereby setting the stage to address both current and future healthcare challenges.

2.2.1 The resilience of the Life Sciences Sector during the Covid-19 pandemic

The first pandemic breakout experienced in Q1 2020 placed significant pressure on major manufacturing industries, yet it presented the life sciences sector with an unprecedented opportunity to innovate and collaborate closely across firms and with regulators, driving tangible progress in the global race to develop vaccines.
Governments and regulators quickly reacted by declaring public health emergency and channeling resources towards the development of prompt medical solutions to the new health threat.
In the United States, at first the FDA issued EUA declarations, allowing unapproved medical products and unapproved uses of approved medical products to be used for the treatment of COVID-19, measure corroborated by the subsequent establishment of the CTAP[79] in order to streamline FDA resources and personnel to guide sponsors through clinical trial design.
In parallel, the NIH created the ACTIV[80] program, which developed a consortium composed of biopharmaceutical companies, philanthropic foundations, and regulatory bodies such as the FDA and the EMA, in order to intensify resource sharing and knowledge interchange with the of expediting the development and regulatory review of potential treatments.
Exhibit 2.2 depicts the biopharmaceutical firms that joined the program, cooperating with each other, and the dedicated five fast-track focus areas.

[79] The Coronavirus Treatment Acceleration Program was issued on March 31, 2020, by the FDA.
[80] Accelerating COVID-19 Therapeutic Interventions and Vaccines program.

Exhibit 2.2 *- NIH ACTIV Program Corporate Sponsors*

Working Group	Scope of Research	Corporate Partners
Preclinical Working Group	# Establishing a centralized process and repository for harmonizing and sharing methods and evaluating animal models; # Extending access to high-throughput screening facilities, especially in biosafety level 3 (BSL-3) labs; # Increasing access to validated animal models; # Enhancing comparison of approaches to identify informative assays; # Generating a process to assess viral variant effects on vaccines and therapeutics.	Pfizer; Gilead Sciences; Dewpoint Therapeutics; Merck & Co., Inc.; GlaxoSmithKline; Roche ; Sanofi; The Jackson Laboratory; Johnson & Johnson
Therapeutics Clinical Working Group	# Establishing a steering committee with relevant expertise to set criteria for and rank potential candidates submitted by industry partners for testing; # Developing a complete inventory of potential candidates with different mechanisms of action and acceptable safety profiles; # Designing, launching, and openly sharing master protocols with agreed-upon endpoints, sampling, and analysis for evaluating candidates; # Using a single control arm to enhance trial efficiency	Genentech; Eli Lilly and Company; Rhythm Pharmaceuticals; Merck & Co., Inc.; Amgen; Pfizer ; Sanofi; GlaxoSmithKline; Johnson & Johnson
Clinical Trial Capacity Working Group	# Specializing in different populations and disease stages; # Leveraging infrastructure and expertise from across NIH and non-NIH networks and clinical research organizations; # Establishing a coordinated mechanism across networks to expedite trials; # Tracking incidence across sites and projecting future capacity.	Genentech; Eli Lilly and Company; Pfizer; Sanofi; Merck & Co., Inc.; Novartis; AstraZeneca
Vaccines Working Group	# Harmonizing efficacy trial designs to facilitate consistent evaluation of vaccine candidates; # Assessing approaches to understand vaccine effectiveness against prevention of infection and transmission; # Creating a collaborative framework to understand correlates of protection across vaccines and share insights into natural immunity.	Moderna Inc.; Pfizer; Sanofi; Merck & Co., Inc.; AstraZeneca; Takeda Pharmaceuticals Co. Ltd.; Novavax Inc.; GlaxoSmithKline
TRACE Working Group	# Monitoring global emergence and circulation of SARS-CoV-2 mutations; # Cross-referencing initial sequence data against database of experimentally or clinically characterized variants; # Characterizing prioritized variants in vitro (outside the animal) and in vivo (inside the animal) through critical-path assays; # Rapidly sharing activity data with the ACTIV membership and scientific community.	Eli Lilly and Company.; Pfizer; Dewpoint Therapeutics; Merck & Co., Inc.; AstraZeneca; Gilead; Moderna Inc.; Vir Biotechnology; Brii Biosciences; The Jackson Laboratory; Roche; Johnson & Johnson;

Source: Personal elaboration based on NIH ACTIV program.

The Trump administration, on the following May 15, announced the creation of the Operation Warp Speed (OWS), one of the most important maneuvers in financial terms, with an estimated public investment of more than $ 18 billion, in order to intensify the discovery and development of vaccines[81]. The Biomedical Advanced Research and Development Authority (BARDA) acted as financial interface between the Congress and the biopharmaceutical companies: by providing funds, knowledge, and coordination for the creation and production of COVID-19 vaccines, treatments, and diagnostics, BARDA was instrumental in Operation Warp Speed. It worked with biopharma companies, providing the funding to scale up production, procure raw materials, and expedite clinical testing. The timely distribution of vaccines was made possible by BARDA's leadership, which made sure that creative solutions were created quickly while upholding safety and effectiveness criteria.

Exhibit 2.3 illustrates the funding allocation provided by BARDA among the biopharmaceutical companies involved in the research and development process of COVID-19 vaccines.

[81] Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force Members, "Operation Warp Speed: Implications for global vaccine security," Lancet Global Health 9, no. 7 pp. E1017–21.

Exhibit 2.3 *- Operation Warp Speed Contracts for Covid-19 Vaccines and Ancillary Vaccination Materials*

Company	Vaccine Type	Contract Value	Specifications
Pfizer/BioNtech	mRNA	$ 5.97B	300 million doses
Moderna	mRNA	$ 4.94B $ 0.95B	300 million doses Development
AstraZeneca	Viral Vector	$ 1.2B	300 million doses
Johnson & Johnson	Viral Vector	$ 1.0B $ 0.46B	100 million doses Development
Novavax	Protein	$ 1.6B	100 million doses
Sanofi	Protein	$ 2.04 $ 0.03B	100 million doses Development
Merck	Viral Vector	$ 0.03B	Development

Source: Congressional Research Service, March 2021.

For the purpose of finding effective solutions for Covid-19 regulatory bodies have not only supported biopharma companies financially and operationally through the establishment of specific programs, as mentioned above, but have supported the industry through the relaxation of bureaucratic requirements for R&D and marketing approval of drugs. In Europe the EMA through its pandemic task force, increased the flexibility of the reviewing process, reducing the time to a maximum of 20 days, reducing the review process of pediatric investigation plans to 20 days, extending the types of trials subject to remote source data verification, and accelerating the marketing authorization process for authorized products and or repurposed for treatment of COVID-19. US regulators at the same time, eased the requirements for good manufacturing practices for ventilators and related PPE, extended the application of the Emergency Use Authorization (EUA) for PPE products, medical devices, drugs and vaccines, postponed routine inspections, and relaxed clinical trial application provisions.[82]

Furthermore, the pandemic emergency presented a unique occasion of cooperation across biotechnological pharmaceutical and medical devices companies, fostering technological spill

[82] Deloitte. 2022. Never the same again. How COVID-19 created seismic change in life sciences regulations.

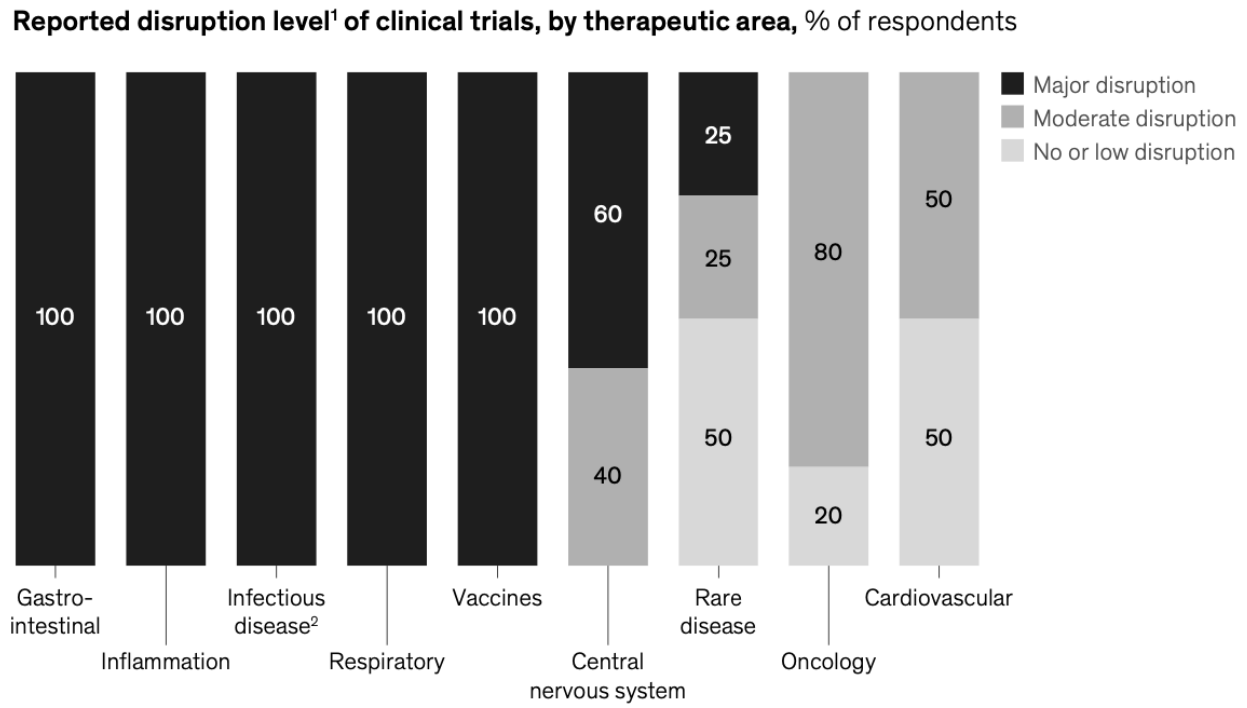
over across the whole industry. In the midst of the constellation of partnerships born during the pandemic breakout, aside from the consortia developed under the ACTIV program, noteworthy is the partnership between BioNTech and Pfizer[83], which teamed up to develop their Comirnaty vaccine with global production amounting to 4 billion doses in 2022, and the the alliance between Eli Lilly and AbCellera for the identification of more than 500 potential therapeutic molecules for COVID-19 treatment[84].

The pandemic period also led to a reshaping of the market dynamics of the life sciences industry by seeing the introduction of new incumbents such as Ford in ventilator manufacturing. Despite the threats to the value chain supply chain, the life sciences industry has therefore benefited from multiple growth opportunities, in terms of process innovations, such as with the adoption of CRISPR[85] technology for gene editing, in terms of modernization of technological infrastructure, and in terms of creating synergies and acquiring scientific knowledge through alliances.

On the other hand, the pandemic period led to diffuse disruptions in the R&D pipeline and supply chain across the life sciences industry. In the first three quarters of 2020, according to a McKinsey survey business-as-usual operations among the surveyed companies in the life sciences sector experienced a contraction by 50%, and at the same time registered a decrease of R&D productivity in a range between 25% and 75% traceable to the unpreparedness for remote work[86]. Nonetheless, the pandemic conjuncture did not affect homogeneous way all the R&D pipelines pertaining to the therapeutic areas of the industry. As shown in Exhibit 2.4, while the therapeutic areas related to vaccines, gastrointestinal, inflammatory, infectious, and respiratory diseases showed severe impacts in R&D processes, being impacted 100% of the surveyed companies; the areas of oncology, cardiovascular, rare disease and central nervous system research proved to be resilient by experiencing low to moderate disruption in R&D processes, with the cardiovascular area standing as the most resilient.

[83] Hopkins, Pfizer lifts COVID-19 vaccine production targets for 2021, 2022.
[84] Eli Lilly and Company, AbCellera and Lilly to co-develop antibody therapies for the treatment of COVID-19, press release, March 12, 2020.
[85] The Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) is a revolutionary gene-editing technology derived from a natural defense mechanism in bacteria.
[86] McKinsey & Company, (2022), COVID-19 implications for life sciences R&D.

Exhibit 2.4 *- Reported Disruption Levels according to Mckinsey's Research*

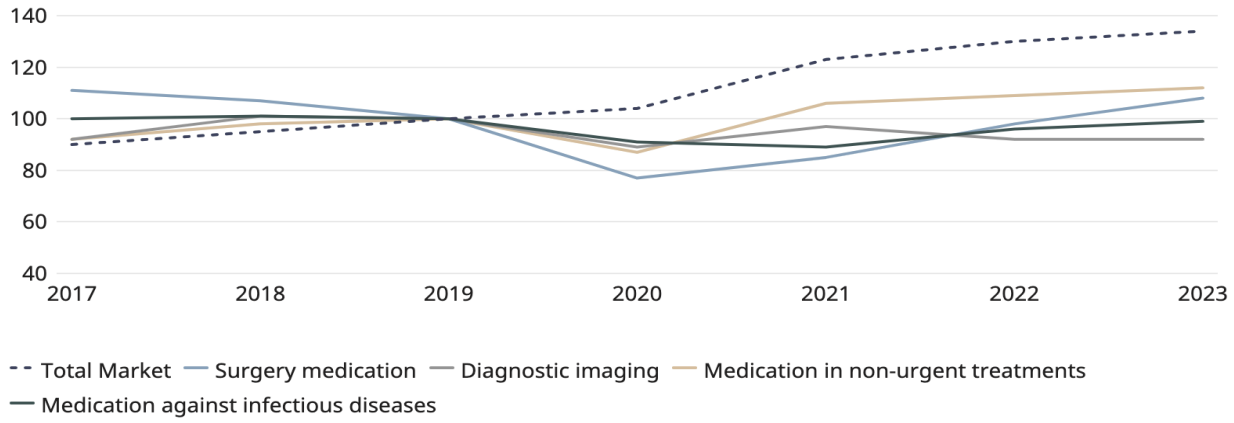


[1]Flow disruption defined as <10% slowing to overall development timeline; moderate disruption defined as 10%–30% slowing to overall development timeline; major disruption defined as >30% slowing to overall development timeline.
[2]Excluding vaccines.

Source: McKinsey & Company, 2022.

During the lockdown, clinical trial processes were suspended for in-person activities, and laboratory analyses faced significant slowdowns, particularly for non-essential drugs unrelated to the health emergency. Consequently, sales reflected the outcomes of R&D processes and were partly influenced by a more intense demand shift toward purchasing EUA products for COVID.

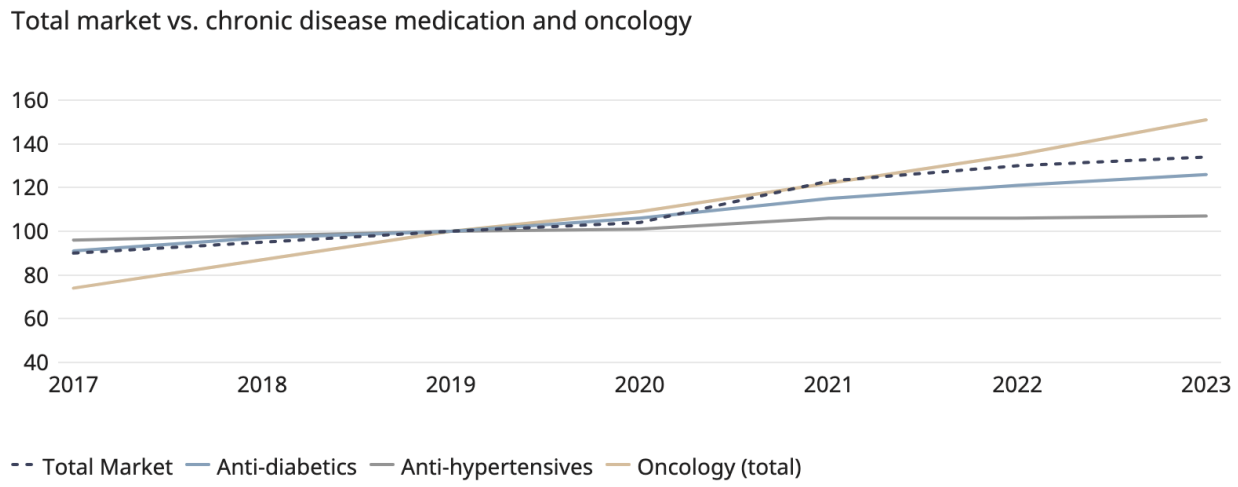
Exhibit 2.5 *- Sales Growth among different treatment areas*



Source: Oliver Wyman, 2022.

As shown in Exhibit 2.5, sales of surgery medications experienced the most severe consequences, with the steepest contraction, taking approximately two years to regain the pre-COVID growth trajectory. Sales of medications for infectious diseases and diagnostic imaging devices remained sluggish during FY 2020 and FY 2021. Particularly, diagnostic imaging devices struggled to recover even by 2023 to pre-pandemic sales levels. In parallel, sales of medication for non-urgent treatments registered an initial contraction due to the negative impact of business-as-usual operations of lockdown measures, followed by a strong recovery, surpassing pre-COVID levels. Conversely, as evidenced in Exhibit 2.6, essential medications, such as those in the oncology therapeutic segment, did not see sales declines. Instead, they outperformed expected market trajectories. This resilience is attributed to companies' ability to integrate new technologies like telemedicine and remote clinical trial monitoring, into their R&D pipeline and operational processes.

Exhibit 2.6 *- Sales Growth Trajectory among Oncology treatments*

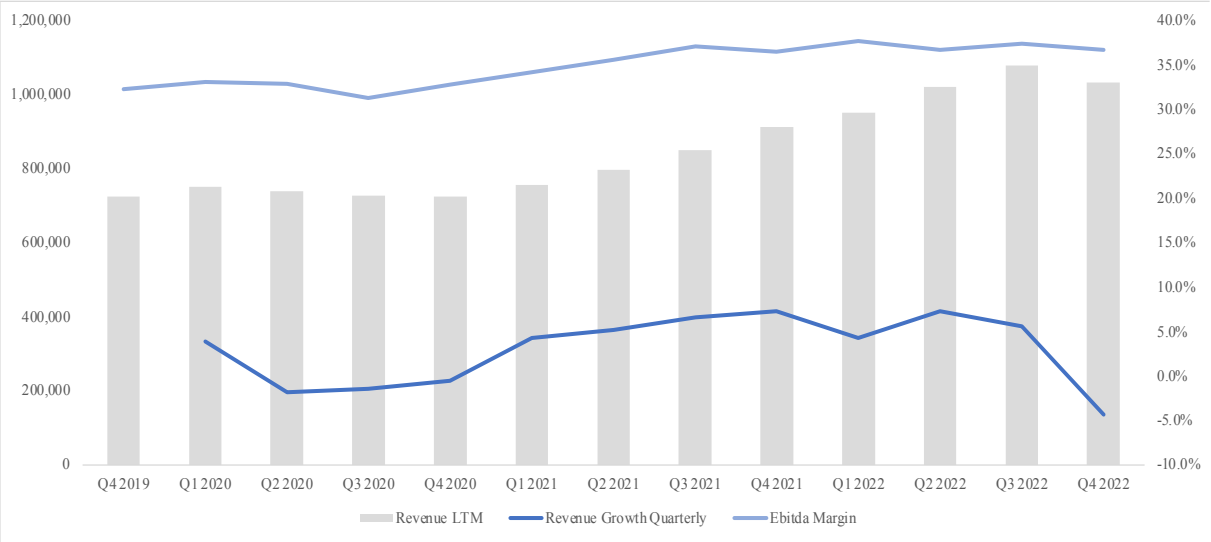


Source: Oliver Wyman. 2022.

The life sciences industry, therefore, challenges the notion of a sector immune to adverse economic cycles. The pandemic demonstrated the granular and destructive impacts of the lockdown on traditional operational workflows. The event reshaped market dynamics, forcing biopharmaceutical companies to innovate to stay competitive through R&D process transformation, strategic alliances, and technology integration, thereby creating potential growth opportunities.

An analysis of the 50 largest publicly listed companies by market capitalization provides insight into the industry's performance during 2020–2022. The data reveals an initial slowdown due to lockdown disruptions, followed by a recovery that led to significant industry expansion.
Exhibit 2.7 illustrates quarterly changes in aggregated LTM revenues for the top 50 companies in the life sciences sector[87].

Exhibit 2.7 *- Aggregated quarterly reported LTM revenues and EBITDA margin of the top 50 capitalized companies in the Life Sciences sector*



Source: S&P Capital IQ.

Based on data sourced from S&P Capital IQ, the aggregated sample recorded sluggish revenues between Q1 and Q3, due to the disruptions in business-as-usual operations as result of lockdown measures. During this period, several companies within the sample were significantly impacted. Pfizer experienced a contraction in sales of -23.7% as of Q3 2020 compared to Q4 2019. Lonza Group reported a decline of -24.8%, Shionogi faced a downturn of -10.2%, Argenx recorded a drop of -22.6%, and Illumina suffered a fall of -12.1%[88].
On the other hand, some companies demonstrated remarkable resilience. Bristol Myers Squibb recorded a 44% expansion in sales, driven by a strong focus on oncology and cardiovascular treatments, particularly the success of its drug *Opdivo*. Moderna achieved a staggering +291.9% increase in sales revenues, propelled by rapid advancements in the development of the COVID-19 vaccine *mRNA-1273*, supported by the Operation Warp Speed funding.

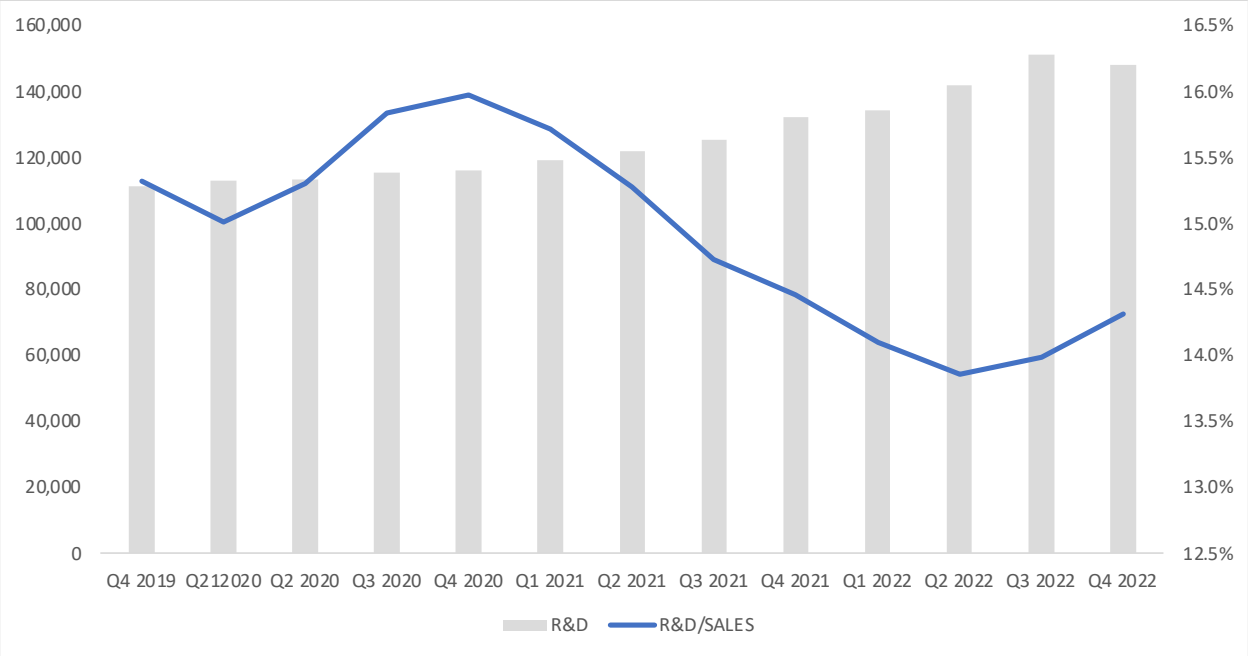
[87] For more information concerning the sample, please refer to Annex A.
[88] Refer to Annex B for the quarterly variation of LTM revenues of the sampled companies.

Similarly, Genmab saw a 106.3% increase in sales, primarily due to the success of *Darzalex* for multiple myeloma treatment. Alnylam also experienced a notable 74.4% growth in revenue, attributed to its innovative RNA interference-based therapies.

Despite the slowdown experienced in the quarters following Q4 2020, the industry demonstrated a strong capacity for recovery, supported by strategic alliances and regulatory backing. By Q3 2021, aggregated revenues had surpassed pre-COVID levels, driven primarily by the commercialization of Covid-related medications. In Q3 2021, several companies recorded exceptional growth in turnover, fueled by the success of their R&D processes. Moderna saw an extraordinary increase of +4,771.5% in revenues compared to Q3 2020, driven primarily by the commercial success of its COVID-19 vaccine. BioNTech experienced an astonishing +8,263% surge in revenues for the same period, largely due to the success of the BNT162b2 COVID-19 vaccine developed in collaboration with Pfizer, which also reported a solid +67.2% revenue increase. Argenx SE saw a remarkable recovery, with a +587.7% rise in revenues compared to Q3 2020, following the FDA approval and commercialization of its autoimmune disease drug, Efgartigimod. Sartorius posted a +51.4% growth, benefiting from the complementarity of its bioprocess solutions, which were instrumental in vaccine R&D processes. Lastly, Alnylam continued its growth trajectory, achieving an impressive +89.3% increase in revenues for the period.

The industry, therefore, managed to build on the capabilities developed during the crisis period and, through strategic alliances and more streamlined regulatory processes, was able to overcome the pandemic and capitalize on an expansion. The sample in question achieved a compounded annual growth rate (CAGR) of 13% for the period from 2019 to 2022, while also improving operational efficiency, attaining an EBITDA margin of 36.7%, up from the pre-COVID margin of 32.3%. This expansion would not have been possible without research and development: during this period, companies made significant investments in R&D, particularly in the race to develop vaccines, which played a pivotal role in their recovery and growth.
Exhibit 2.8 shows the trend in research and development (R&D) expenses for the selected sample of companies and the evolution of the R&D expenses-to-sales ratio. Initially, companies increased their R&D spending, while revenues declined due to operational slowdowns caused by the lockdown, which led to a spike in the R&D-to-sales ratio in Q4 2020.

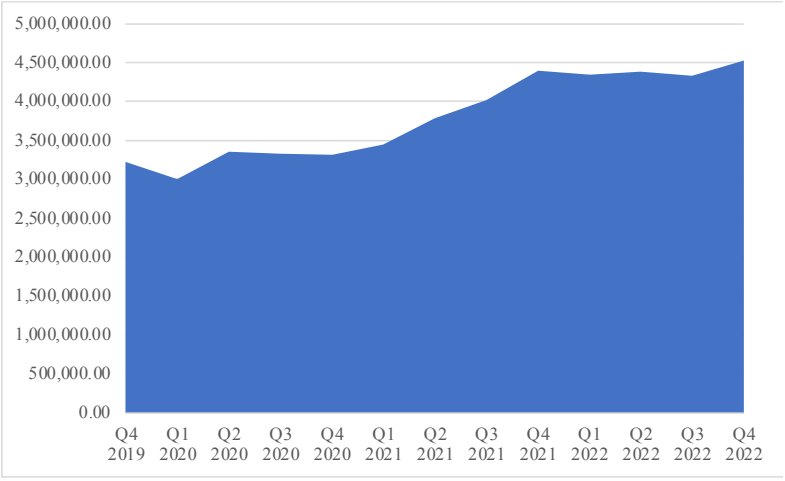
Exhibit 2.8 *- Aggregated quarterly reported R&D expenses and R&D/Sales ratio of the top 50 capitalized companies in the Life Sciences sector. Figures are reported in millions of euros.*



Source: S&P Capital IQ.

Once successes in R&D were achieved and COVID-related drugs and supporting medical devices were patented, revenues began to expand. While R&D expenses continued to rise, the R&D-to-sales ratio started to decrease, reaching approximately 14% in Q2 2022, highlighting higher returns on R&D investments. Moreover, the resilience of the life sciences sector, the remarkable performance achieved during this period, and the groundbreaking discoveries of essential drugs for society have been mirrored in stock market performance, as illustrated in Exhibit 2.9.

Exhibit 2.9 - *Market Capitalization reported quarterly of the top 50 capitalized companies in the Life Sciences sector. Figures are reported in millions of euros. Source*



Source: S&P Capital IQ.

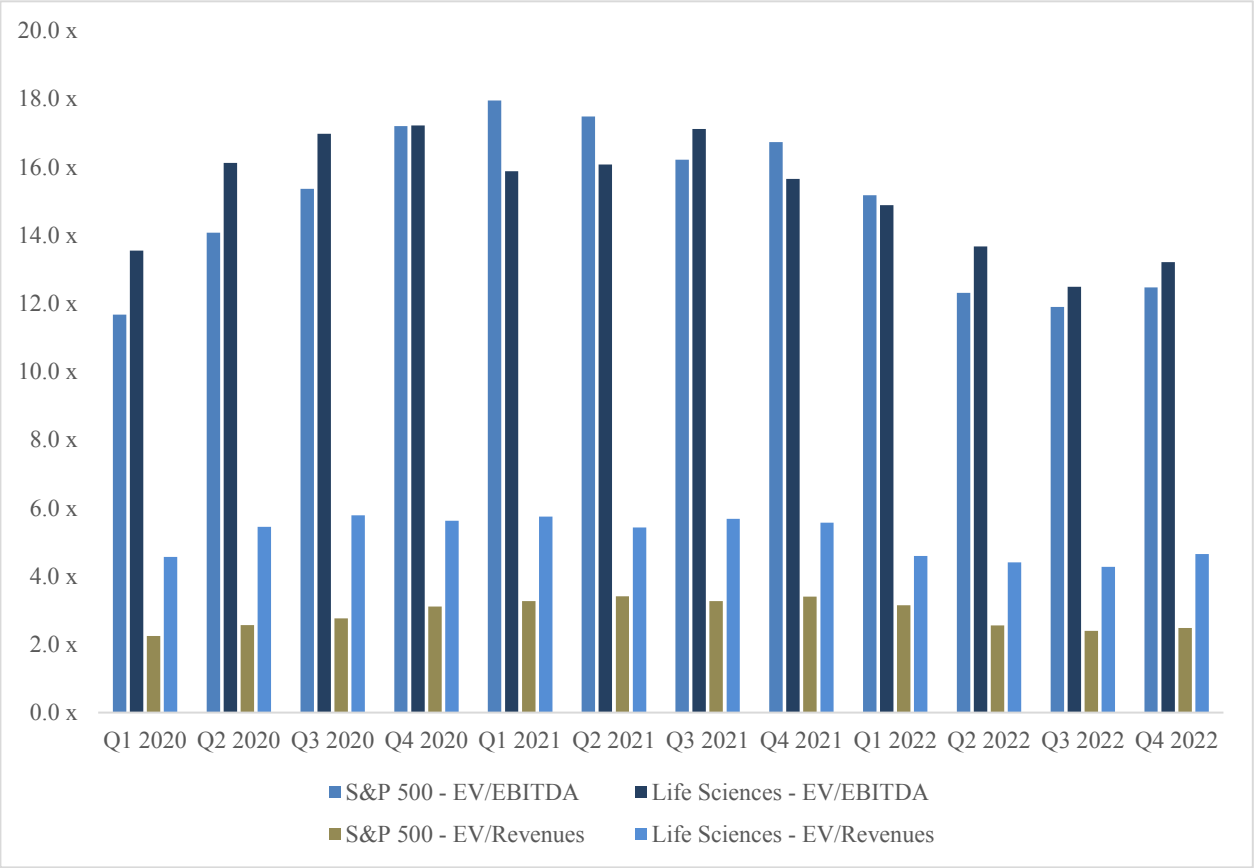
As shown, market capitalization experienced significant growth, initially driven by speculation and later supported by the solid fundamentals of the companies. For the aggregate of sampled companies, as of Q4 2022 market capitalization experienced an overall increase of 40.2% compared to Q4 2019. The growth in market capitalization of companies involved in the R&D pipeline for medicines and devices aimed at addressing the health emergency strongly supported the industry's recovery. Moderna, for example, saw a dramatic increase in market cap, rising by +1,011.6%, largely driven by a +2,207.5% surge between Q3 2021 and Q4 2019, before experiencing a contraction due to the declining efficacy of its vaccine against emerging COVID-19 variants.

Similarly, BioNTech saw a +400% increase in market cap, driven by strong stock performance, fueled by the success of its COVID-19 vaccine developed in collaboration with Pfizer. Eli Lilly also recorded a significant market cap increase of +189.3%, thanks to the strength of its R&D efforts during the pandemic, culminating in effective treatments for obesity (Mounjaro). Novo Nordisk experienced a +134.1% rise in market cap, driven by the success of its drugs Ozempic and Rybelsus. Finally, AbbVie saw a +129.1% increase in market cap, reflecting a 183% expansion in revenue, achieved by focusing on oncology medications during the pandemic period.

The simultaneous increase in market capitalization reflected growth in fundamental metrics, such as revenue and operational efficiency, particularly in EBITDA margin. The EV/EBITDA and EV/Revenue multiples mirrored this expansion, especially during the period between Q1 and Q3 2020, which was impacted by the surge in market cap driven by vaccine race speculation and the subsequent contraction of metrics due to the lockdown-induced slowdowns. As these metrics began to grow, the multiples deflated, thanks to a simultaneous cooling of speculative activity in the equity market.

The surprising insight is not only the sector's resilience during the pandemic's adversities but its ability to consistently outperform the S&P 500 across multiple quarters during the period in question. Exhibit 2.10 illustrates the trend in trailing median EV/EBITDA and EV/Revenue multiples for the sample, compared to the median multiples of the S&P 500.

Exhibit 2.10 *- Median EV/EBITDA LTM and EV/Revenue LTM Trailing Multiples of the top 50 capitalized companies in the life sciences sector compared to the median EV/EBITDA LTM and EV/Revenue LTM trailing multiples of the S&P 500.*



Source: S&P Capital IQ.

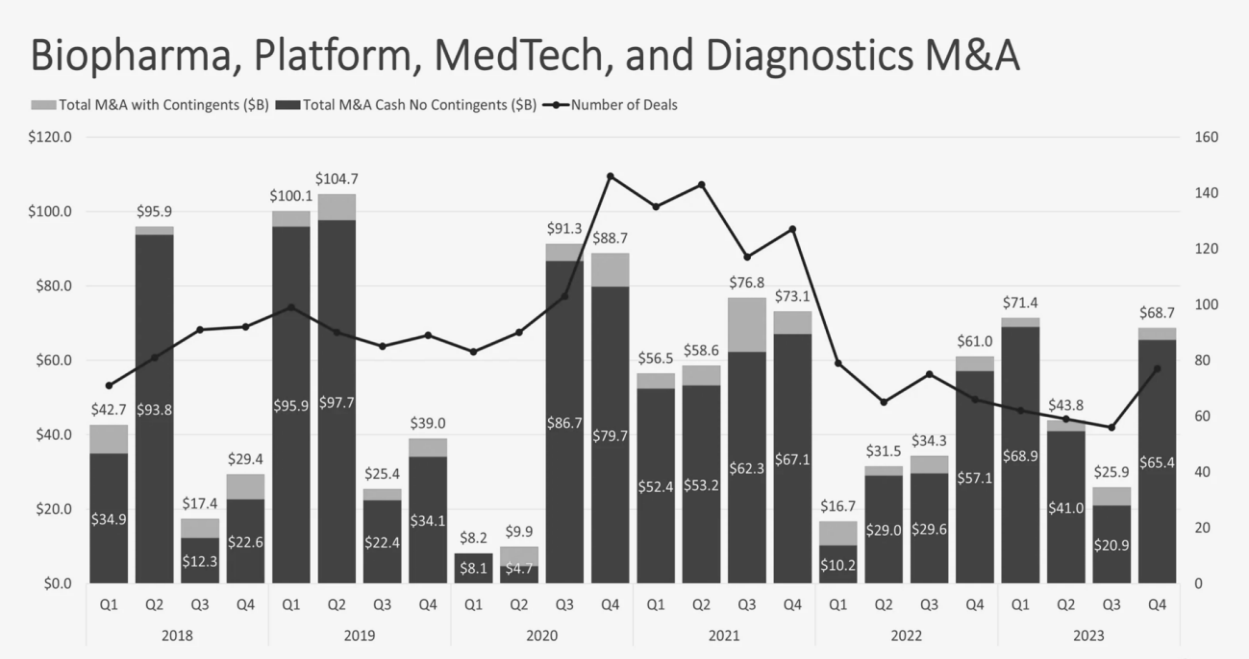
The life sciences sample consistently showed median EV/Revenue multiples above the S&P 500 median, with a median EV/Revenue LTM multiple ranging between 4.28x and 5.78x. In parallel, EV/EBITDA multiples outperformed the S&P 500 during the quarters corresponding to the first pandemic breakout (in Q1 2020 13.55x compared to 11.67x, in Q2 16.12x compared to 14.07x, and in Q3 16.97x compared to 15.36x) and again in Q3 2021 (17.12x vs 16.21x), during the height of the initial vaccine rollout. By Q4 2022, the life sciences sector had achieved a median multiple higher than the S&P 500 median, standing at 13.22x.

This overperformance highlights the sector's remarkable ability to confront adversity by integrating new processes and technologies into its R&D and operational pipelines. While several industries were experiencing profound slowdown, the life sciences industry thrived and emerged as one of the best-performing sectors relative to the S&P 500.

2.2.2 Reshaping the Market through M&A Activity: The Post-Pandemic Era

With the pandemic behind us, the life sciences industry continues to explore diverse opportunities to build upon the competencies and technologies developed during the preceding period, driving growth in an ever-changing environment. M&A activity in the life sciences sector experienced significant growth in 2021, both in the number of deals and in overall deal value. Low interest rates facilitate debt financing, accelerating deal making and favoring cash acquisitions by major pharmaceutical buyers. Notable transactions included Merck's acquisition of Acceleron Pharma for $11.5 billion, Pfizer's acquisition of Arena Pharmaceuticals for $6.7 billion, and Sanofi's agreement to acquire Kadmon for $1.9 billion. The surge in M&A activity was driven not only by favorable financing conditions but also by a strategic focus on integrating digital processes and technologies into early-stage R&D and expanding pipeline assets. A prime example is Thermo Fisher's $17.4 billion acquisition of PPD, one of the leading global CROs, aimed at enhancing R&D capabilities. However, as shown in Exhibit 2.11, the tightening of monetary policies to combat inflation led to a sharp decline in M&A activity within the life sciences sector, reflected in both the number of deals and their cumulative value: megadeals declined during 2022, with deals above $1 billion reducing by 60% with respect to 2021, and mainly focused on pre-clinical and late-stage oncology drugs, such as the acquisition of Turning Point Therapeutics for $ 6.05 billion carried out by Bristol-Myers Squibb in June 2022.

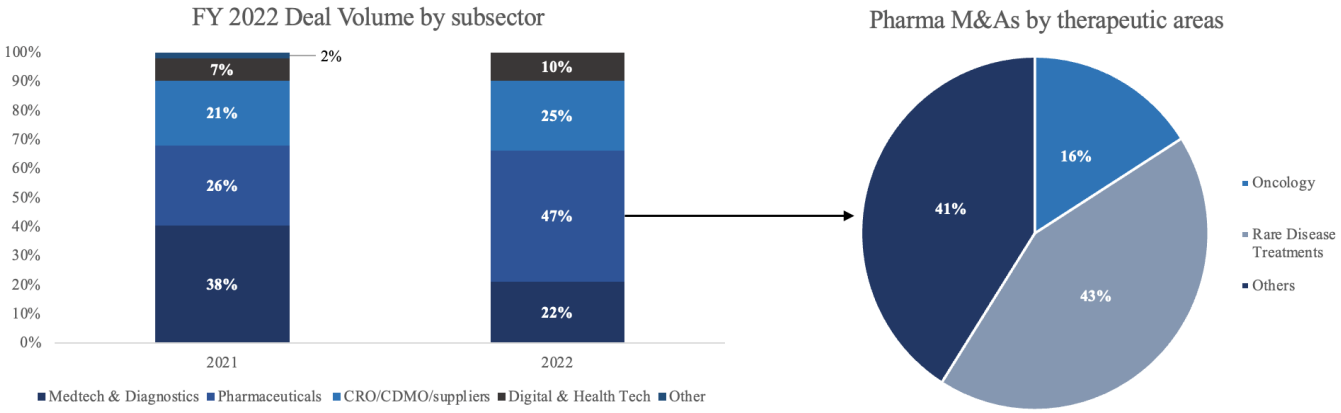
Exhibit 2.11 *- Dealmaking in the Biopharmaceutical Sector from 2018-2023*



Source: DealForma. 2024.

As fear of recession and future adverse economic condition diffused in 2022, milestone payments and earnouts surged amounting to 27% of total deals in 2022.[89] As shown in Exhibit 2.12, deal making fell across all the subsectors of the life sciences industry, with pharmaceutical deals assuming major preponderance recording 47% of the aggregated amount of deal closed, with rare diseases treatment and commercial or late-stage oncology products being the major focus of pharma deals with a cumulative percentage of 59%.[90]

Exhibit 2.12 *– M&A activity decomposed by subsector of the Life Sciences Industry*



Source: Personal elaboration based on Deloitte's report "M&A trends in life sciences: Deal-making 2022".

A noteworthy trend has been the growing prominence of acquisitions targeting CROs and CDMOs, which accounted for 25% of total deal volume. By 2022, the deal value for CRO and CDMO targets reached $21 billion, marking a significant increase from the $15.5 billion recorded in 2021. This shift underscores a heightened emphasis by companies on streamlining operations, particularly in R&D, to reduce costs through the externalization of research activities.

Throughout 2023, life sciences companies continued to navigate external risks stemming from geopolitical uncertainties and escalating inflation, alongside increasingly stringent interest rate environments. Against this backdrop, the industry exhibited several trends that shaped growth strategies, notably through bolt-on acquisitions designed to enhance operational efficiencies and expand capabilities.

[89] Deloitte. 2023. M&A trends in life sciences: Deal-making in 2022.
[90] Ibid.

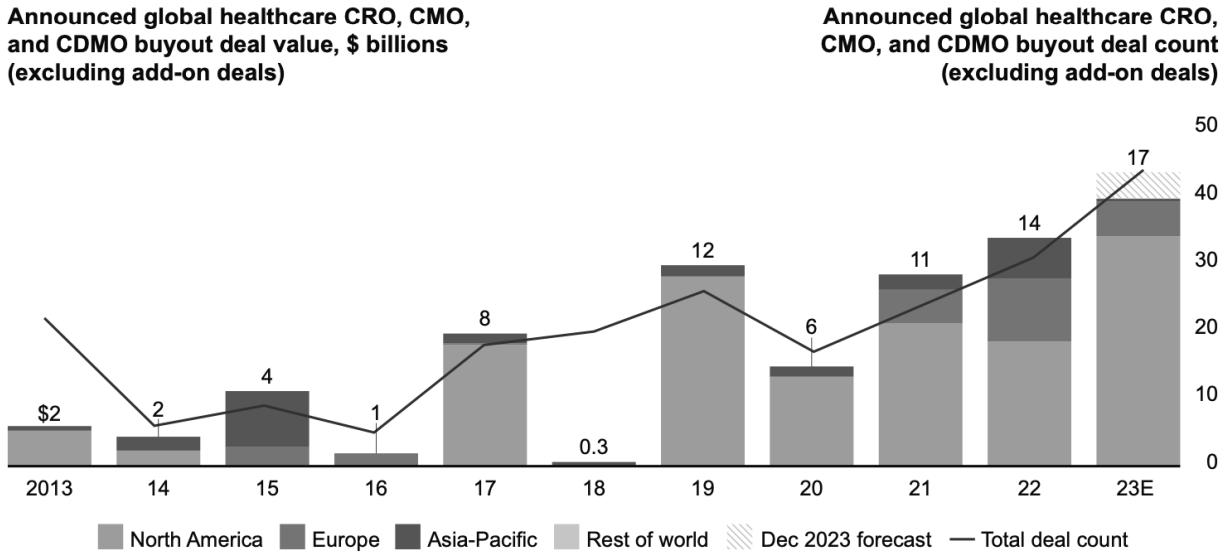
In August 2022, the Biden Administration enacted the Inflation Reduction Act (IRA), heralded as "the most significant action Congress has taken on clean energy and climate change in the nation's history." The legislation aims to allocate federal funding to reduce carbon footprint emissions, lower healthcare costs, secure financing for the IRS, and enhance taxpayer oversight. A groundbreaking provision within the IRA amends the Medicare Part D program by altering the longstanding "non-interference" clause, which governed interactions between the HHS Secretary, drug manufacturers, pharmacies, and prescription drug plan sponsors. Under the new rules, the HHS Secretary gains the authority to negotiate market prices for certain drugs directly with pharmaceutical companies. To be eligible for negotiations, drugs must meet specific criteria: they must rank among the 50 costliest medications for the Medicare Part D and Part B programs, lack biosimilar competitors, and have been on the market for at least seven years for small molecules or 11 years for biologics. Congress has already released a list of the first 10 drugs subject to price negotiation, with pricing changes set to take effect in January 2026. This list will expand to include 60 drugs covered by Medicare Part D and Part B programs by January 2030. Additionally, the IRA introduces a provision capping price increases, tying them to the Consumer Price Index (CPI) to mitigate future Medicare expenditures and curb inflationary pressures. The introduction of the Inflation Reduction Act (IRA), set to take effect in 2026, is expected to significantly impact profitability, with margins projected to decrease by approximately 20% for drugs in therapeutic areas heavily utilized by older adults, such as oncology and Alzheimer's treatments—key beneficiaries of the Medicare Part D program.

At the same time, oncology and rare disease treatments, which are characterized by low baseline rebates, will face additional pressure from price negotiations. The resulting reductions in drug pricing will disproportionately affect these therapeutic areas, given their current reliance on premium pricing models. Furthermore, the implementation of time constraints on pre-negotiation periods—set at 7 years for small molecules and 11 years for biologics—will curtail the revenue-generating lifespan of these drugs. Future cash flows from product lifecycles are anticipated to shrink, with revenue declines of 5-6% for small molecules and 3-4% for biologics over their lifetimes. With R&D costs expected to remain unchanged, the net present value (NPV) of projects in these areas will face significant erosion.[91]

[91] Boston Consulting Group. September 2023. Navigating the Inflation Reduction Act's Impact on Drug Pricing an Innovation.

Under this new paradigm, biopharmaceutical companies responded swiftly by readjusting their growth strategies. They placed particular emphasis on redefining M&A targets, accelerating R&D pipelines, implementing changes in financing to maximize research and development investments, and actively seeking external partnerships to share risks and potential rewards in the research and development process. The need to streamline R&D processes has increasingly manifested in strategic acquisitions targeting CROs and CDMOs, which in 2023 continued their growth trajectory from 2022, especially attracting the interest of private equity funds. Exhibit 2.13 highlights increasing prominence of CROs and CDMOs in the private market, as contract research and contract manufacturing is playing a crucial role in the value chain of life sciences industry, cumulative deal values are experiencing a drastic surge, with great focus in North America.

Exhibit 2.13 *- CDMO's buyout per Geography*



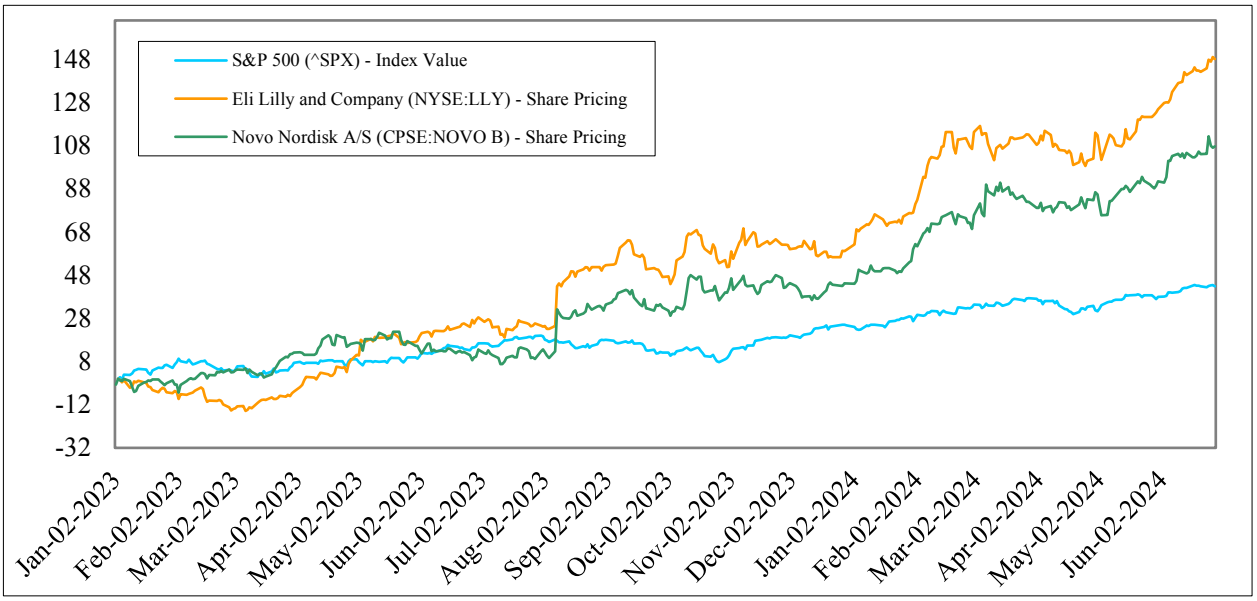
Source: Bain & Company. 2024

The surge in deal making involving CRO and CDMO targets can also be attributed to the remarkable success of GLP-1 therapies, which have proven highly effective in treating obesity and diabetes. Developing these therapies required significant contributions from CDMOs specializing in peptides and biologics.[92] Indeed, during 2023, drugs that initially were developed to treat type 2 diabetes, are increasingly formulated as weight loss medications: Eli Lilly and Novo Nordisk have directed significant R&D investments toward weight management medications, developing

[92] Bain & Company. 2024. Global Healthcare Private Equity Report.

successful drugs such as *Zepbound*[93], derived from the capabilities inherited form the development of *Mounjaro*, and *Ozempic*[94]. The remarkable success of these drugs has led valuations of these companies to a historical run, capitalizing on staggering stock returns, overperforming the S&P 500 index, thereby attracting the attention of several competitors on this new therapeutic area with high untapped potential.

Exhibit 2.14 *- Eli Lilly and Novo Nordisk stock price compared to S&P 500*



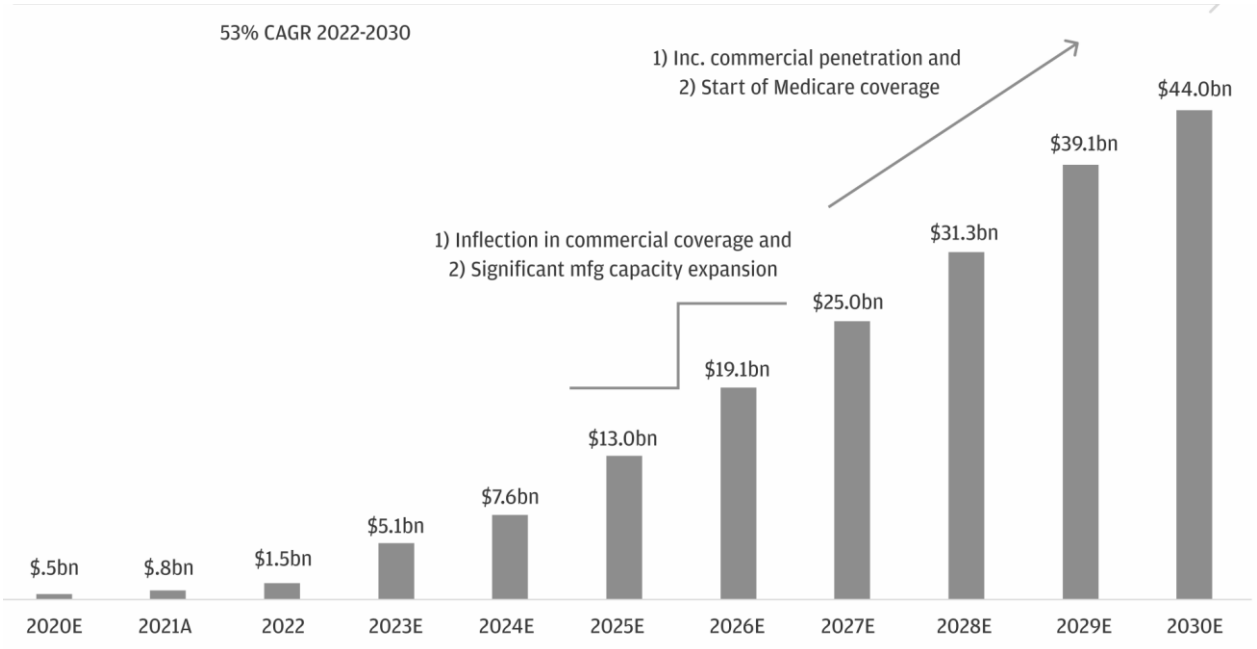
Source: S&P Capital IQ

Medications against obesity may be commencing their process of becoming mainstream in the market, establishing a potential $ 44.0 billion worth market by 2030 according to J.P. Morgan. Exhibit 2.15 reports the expected market expansion for GLP-1s in the United States from 2022 to 2030, which will involve a Compounded Annual Growth Rate of +53%.[95] This market growth is largely attributed to the disruptive potential of GLP-1 drugs, which address not only obesity but also cardiovascular diseases, effectively centralizing the treatment of these conditions into a single therapeutic approach. Moreover, the sector is currently highly lucrative due to the exclusivity of

[93] Zepbound, has been developed by Eli Lilly, based on *tirzepatide*, it has been proved to be successful in lowering weight and cholesterol if combined with appropriate physical exercise.
[94] Novo Nordisk developed Ozempic, based on *semaglutide* injections, it is proved to lower A1C, lower weight, and lower the likelihood of major cardiovascular diseases.
[95] J.P. Morgan. November 2023. The increase in appetite for obesity drugs.

these medications. For instance, Zepbound costs $1,086.37 per fill[96], while Ozempic is priced at $968.52 per fill[97].

Exhibit 2.15 *– Expected market expansion of GLP-1 medications*



Source: J.P. Morgan. 2023.

This thirst for profitability is driving numerous biotech firms to enter the market, experimenting with new formulations. Unsurprisingly, venture capital activity has undergone a significant shift over the past year, channeling substantial investments into biotech startups focused on the early - to late-stage development of GLP-1 drugs. In light of these trends, M&A activity in 2023 recorded a total of 254 deals, with an aggregate announced value of $209.8 billion, as illustrated in Exhibit 2.11. This marks a significant increase compared to 2022, which saw a total disclosed value of $143.5 billion. Exhibit 2.16 highlights the top 10 mega-deals, each exceeding $3 billion in value. Some of these deals targeted companies with approved oncology assets, particularly in the ADC (antibody-drug conjugates) space. Notable examples include the merger of Celltrion Healthcare and the acquisition of Seagen by Pfizer, which remains under regulatory review. Other deals focused on CROs with expertise in protein-based drug therapy development, such as Danaher's acquisition of Abcam.

[96] Eli Lilly Corporate Webiste. How much should I expect to pay for Zepbound® (tirzepatide)?.
[97] Novo Nordisk Corporate Website.

Exhibit 2.16 *– The 10 mega-deals of 2023.*

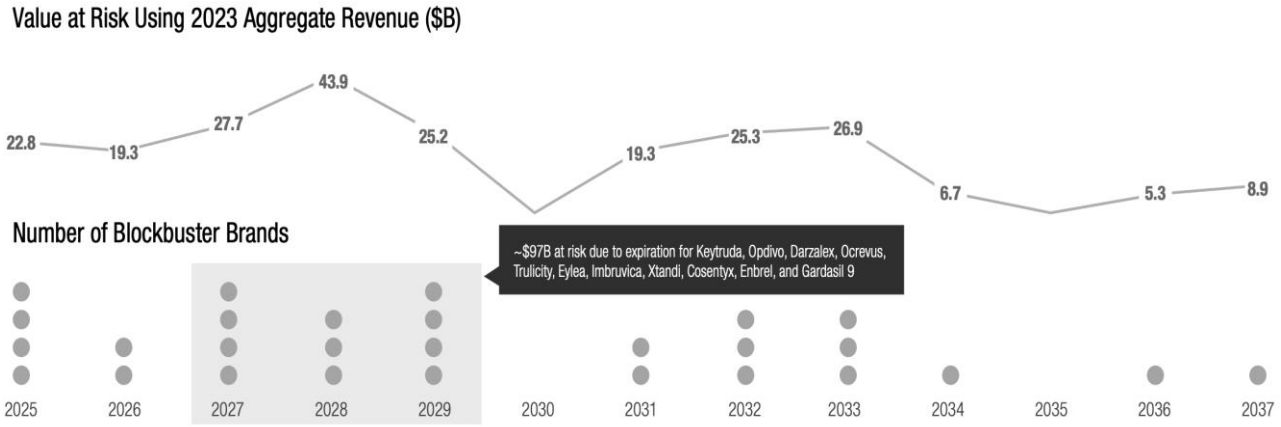
M&A Closed Date	Target/ Issuer	Buyers/ Investors	Total Transaction Value
14/12/2023	Seagen Inc.	Pfizer Inc. (NYSE:PFE)	44551.20
06/10/2023	Horizon Therapeutics Public Limited Company	Amgen Inc. (NasdaqGS:AMGN)	30245.79
16/06/2023	Prometheus Biosciences, Inc.	Merck & Co., Inc. (NYSE:MRK)	10876.63
26/09/2023	Reata Pharmaceuticals, Inc.	Biogen Inc. (NasdaqGS:BIIB)	7830.84
14/12/2023	Telavant Holdings, Inc.	Roche Holding AG (SWX:ROG)	7250.00
11/07/2023	IVERIC bio, Inc.	Astellas US Holding, Inc.	6024.03
06/12/2023	Abcam Limited	Danaher Corporation (NYSE:DHR)	5999.21
28/12/2023	Celltrion Healthcare Co., Ltd.	Celltrion, Inc. (KOSE:A068270)	5340.52
01/12/2020	Asklepios BioPharmaceutical, Inc.	Bayer Aktiengesellschaft (XTRA:BAYN)	4000.00
15/01/2024	Taisho Pharmaceutical Holdings Co., Ltd.	Otemon Co., Ltd.	3722.79

Source: S&P Capital IQ.

Despite the challenges posed by rising interest rates, M&A activity in the life sciences sector has experienced a growth compared to 2022, driven in part by the need to offset losses due to patent expirations. As patents near expiration, biopharmaceutical companies have increasingly pursued bolt-on acquisitions to mitigate the revenue decline associated with the loss of exclusivity.

Between 2024 and 2037, it is projected that pharma companies could lose $189 billion in revenue due to expiring patent protections.[98] Exhibit 2.17 highlights the anticipated timeline for the loss of exclusivity for blockbuster drugs (i.e., those with annual sales exceeding $1 billion) from 2023 through 2037 and the related value at risk in terms of revenue.

Exhibit 2.17 *– Expected Loss of Exclusivity of main blockbuster drugs 2025-2037.*



Source: Alvarez & Marsal. 2024.

[98] Alvarez & Marsal. *2024* Biopharmaceutical M&A and VC insights.

Specifically, the most severe backlog from this massive patent cliff is expected to be from 2027 to 2029, when the following blockbuster drugs will expire: *Keytruda* by Merck that realized $ 25.01billion in sales in 2023, *Darzalex* by J&J that realized $ 9.74 billion in 2023, *Gardasil 9* by Merck ($ 8.90B in sales in 2023), *Opdivo* by Bristol-Myers Squibb that realized $ 9.01 billion in sales in 2023, , *Ocrevus* by Roche ($ 7.1B in sales in 2023), *Trulicity* by Eli Lilly ($ 7.13B in sales in 2023), *Xtandi* by Astellas and Pfizer ($ 6.26B in sales in 2023), *Cosentyx* by Novartis ($ 4.98B in sales in 2023), *Imbruvica* by AbbVie and J&J, *Enbrel* by Amgen ($ 3.7B in sales in 2023).[99]

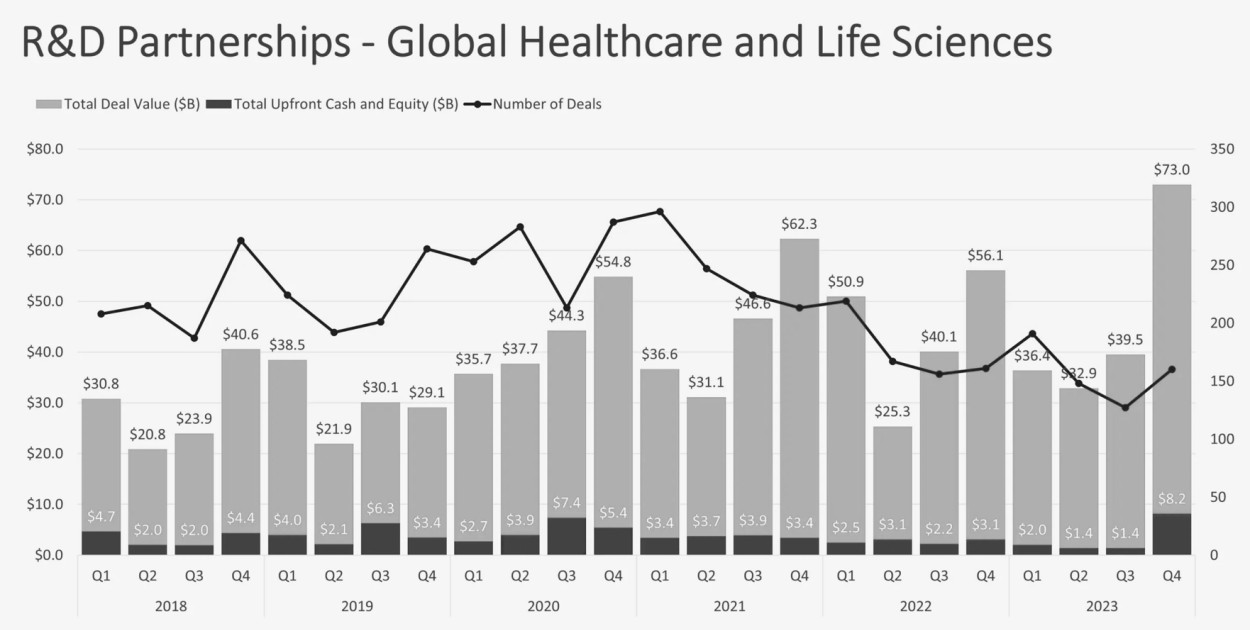
Anchoring the benchmark to revenue figures derived from the specific drug sales in 2023, the companies most impacted by the patent cliff are Merck and Bristol Myers Squibb. Merck is affected by the expiration of *Keytruda* and *Gardasil 9* patents in the United States in 2028, representing a combined revenue of $33.91 billion in 2023. Similarly, Bristol Myers Squibb faces the expiration of patents for *Eliquis* and *Opdivo*, expiring in the United States in 2026 and 2028, respectively, accounting for a total revenue of $21.22 billion in 2023.[100]

Facing the imminent risk posed by the loss of exclusivity of the Keytruda patent, one of the leading blockbuster drugs for oncology treatments, Merck has opted to expand its oncology R&D pipeline through two strategic acquisitions. Merck acquired the rights to CN201 Investigational B-Cell Depletion Therapy from Curon Biopharmaceuticals for $700 million in cash plus milestone payments of $600 million, combined with the acquisition of Modifi Biosciences, a leader in developing direct DNA modification cancer therapeutics, for a total of $1.3 billion[101]. Similarly, Bristol-Myers Squibb initiated its defensive strategy against the loss of exclusivity for Opdivo, a blockbuster drug approved for the treatment of multiple carcinomas, by strengthening and diversifying its oncology portfolio through the acquisition of Mirati Therapeutics for a total consideration of $6.32 billion[102].

These macro drivers have further boosted R&D partnership activity among biopharmaceutical companies, leading to an increase in deal value compared to 2022. As can be inferred from Exhibit 2.18, the total deal value of R&D partnerships in 2023 reached $181.7 billion, with $13.1 billion in upfront cash, exceeding pre-pandemic levels despite a decrease in deal volumes.

[99] Gardner, J. 2023, March 6. Drug patents protect pharma profits. Track when they'll expire. BioPharma Dive.
[100] Ibid.
[101] Merck Corporate Website. Press Releases.
[102] Bristol-Myers Squibb Corporate Website. Press release.

Exhibit 2.18 *– R&D Partnerships in the Life Sciences Sector, 2018-2023.*



Source: DealForma 2024

This growth is evident when compared to 2022, which recorded a total announced deal value of $172.1 billion and $10.9 billion in upfront cash.[103] During this period, the loss of exclusivity (LoE) of patents played a significant role in driving R&D partnerships. For instance, to mitigate the impact of the Keytruda LoE, Merck acquired global development and commercialization rights for three of Daiichi Sankyo's DXd antibody-drug conjugate (ADC) candidates (*Patritumab Deruxtecan, Infinatamab Deruxtecan, and Raludotatug Deruxtecan*) for a total potential consideration of up to $22 billion[104]. Similarly, Bristol-Myers Squibb, to address the LoE of Opdivo, entered into a licensing agreement with Sichuan Biokin for the development and commercialization of BL-B01D1, an ADC for the treatment of lung, urothelial, and nasopharyngeal carcinomas.[105]

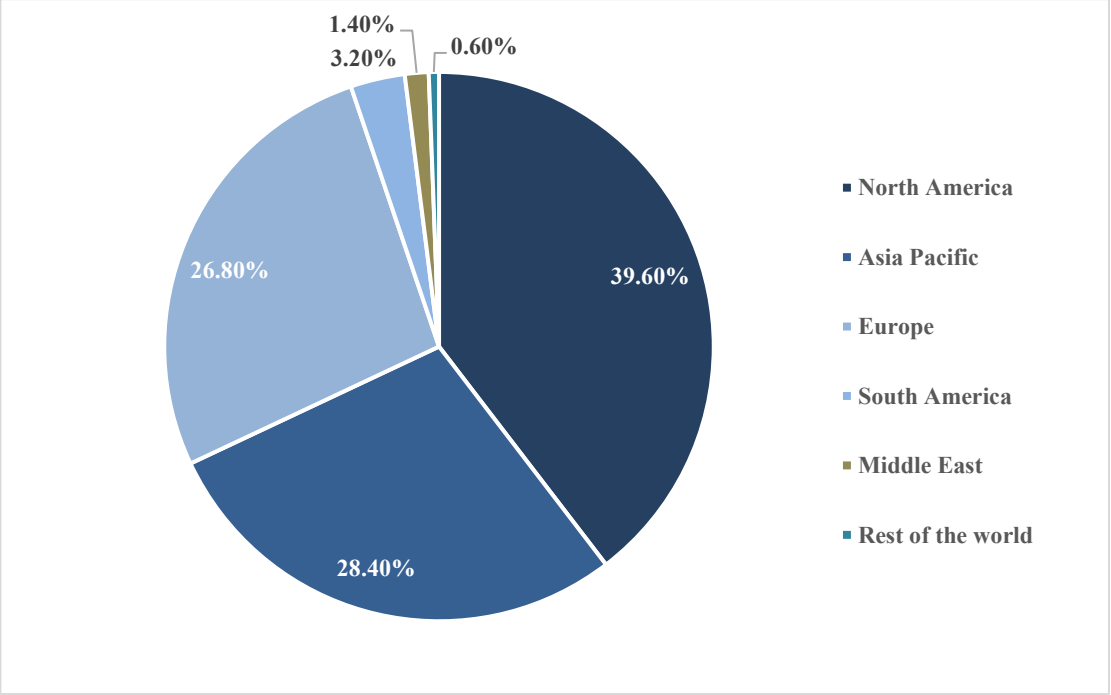
This trend underscores the strategic importance of M&A and R&D agreements as a means to replenish pipelines and sustain growth in the face of looming patent cliffs, which will imply potential increase in terms of deal volume in the imminent future.

[103] Chris Dokomajilar. January 2024. Healthcare and Life Sciences Deal and Funding Review of 2023. DealForma.
[104] Merck Corporate Website. Press Release.
[105] Bristol-Myers Squibb Corporate Website. Press Release.

2.2.3 Future Outlook of the Life Sciences Sector

The global pharmaceutical market reacted to this new paradigm registering a sluggish yearly growth of 0.1% for 2023, being impacted by inflationary pressure as it pushed consumers to cut on non-essential healthcare spending. Notwithstanding the hardships posed by the macroeconomic developments, the market maintained the growth trajectory thanks to technological advancements specifically for personalized medicine. As depicted in exhibit 2.19, North America continues to dominate the market, holding 39.6% share of the market, while Asia-Pacific continues its strong growth realizing a 6.5% CAGR between 2018 and 2023, thereby holding the second largest market share, standing at 28.4%, surpassing Europe, that holds 26.8% of the market share.[106]

Exhibit 2.19 *- Global pharmaceuticals market geography segmentation: % share, by value, 2023*



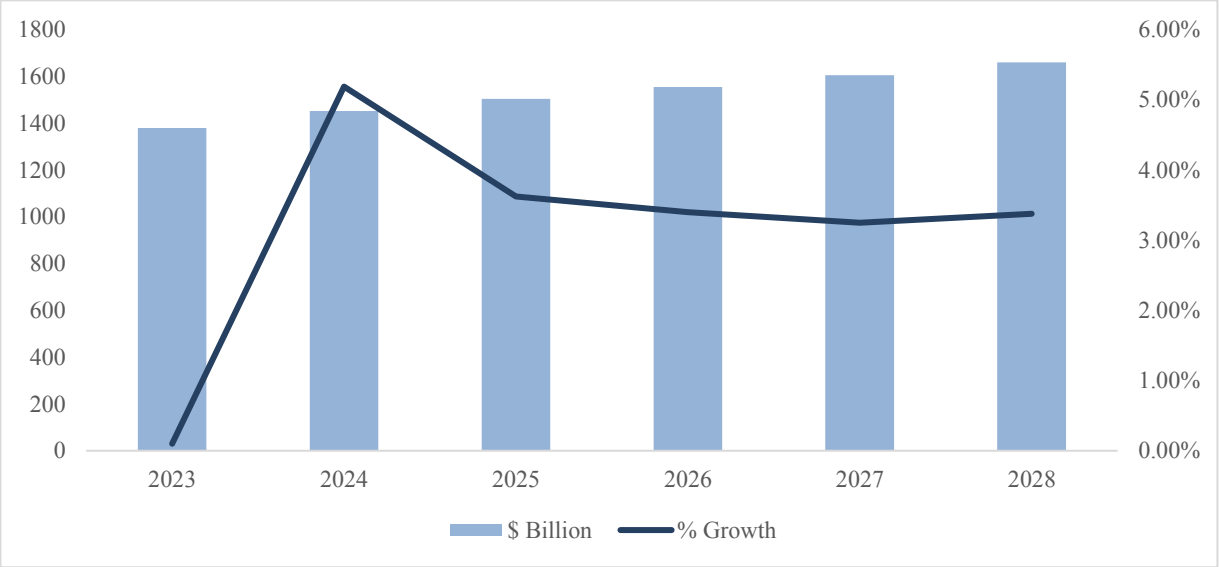
Source: MarketLine. 2024.

The global pharmaceutical market is expected to accelerate its growth in the following 2023-2028 period, mainly traceable to consistent aging population across the western economies, widespread of chronic diseases, and new medical treatments such as telemedicine. As shown in Exhibit 2.20, for the period 2023-2028 the global pharmaceutical market is expected to reach a CAGR of 3.8%

[106] MarketLine Industry Profile. September 2024. Global Pharmaceuticals.

driving the market to a value of $ 1,660 billion as of 2028, with Asia-Pacific and North America pushing the market, as they are expected to register a CAGR of 4.4% and 4.2% respectively.

Exhibit 2.20 *- Global pharmaceuticals market value forecast: $ billion, 2023–28*



Source: MarketLine. 2024.

The Italian pharmaceutical market registered a compounded annual growth rate of 4.8% between 2018 and 2023, demonstrating a more intense growth with respect the French market, with a CAGR of 2.5% for the same period, being only second to German market in terms of growth, which recorded a CAGR of 5.2%.

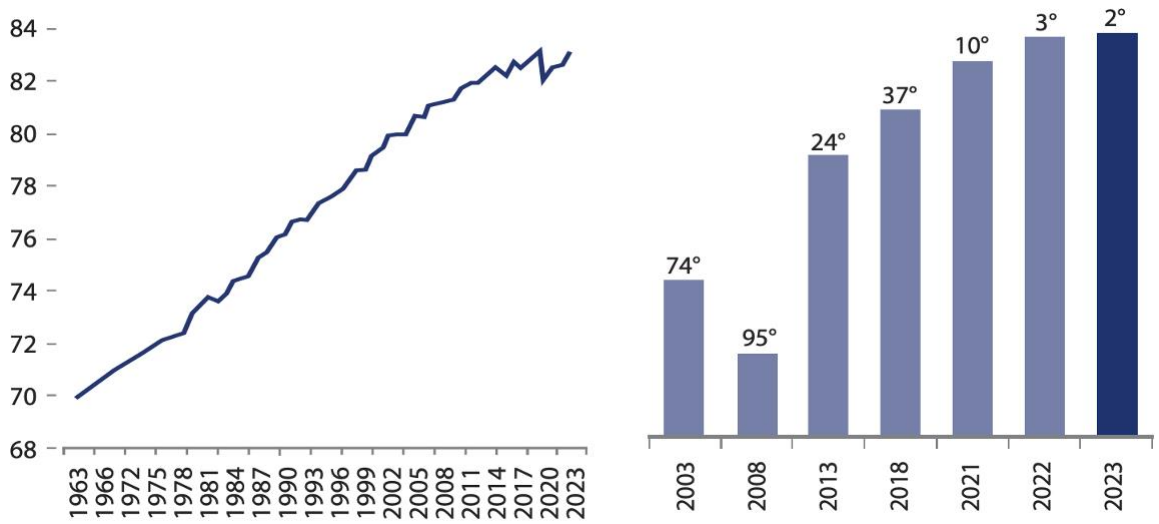
The Italian pharmaceutical market owes its growth to its population's demographic structure, being one of the countries with the highest concentration of elderly citizens. It is growing at a significantly faster pace than its European peers. According to ISTAT, in 2022, Italy recorded the highest aging index in Europe, with 187.6 elderly people per 100 young individuals, followed by Portugal (184.9) and Greece (166.1).[107] This demographic represents 24% of the Italian population, based on World Bank data.

This aging index results from both a declining birth rate, which has decreased by 34.2% since 2008, and improvements in average life expectancy. As shown in Exhibit 2.21, Italy's average life expectancy has expanded significantly over the past 60 years, increasing by over 12 years. With an increasingly aging population, the demand for medical and pharmaceutical treatments is

[107] Noi Italia 2024, Popolazione. 2024. Istat.

expected to grow steadily, strongly supporting the expansion of the Italian pharmaceutical market. The pharmaceutical industry is a strategical sector of Italy's economy, throughout 2003 to 2023 the pharmaceutical exports surged, thereby playing a vital role in country's exports: according to ISTAT in 2003 the pharmaceutical industry ranked 74th among sectors in terms of net foreign trade balance, and by 2023, it had risen dramatically to occupy second place.

Exhibit 2.21 *- On the left average life expectancy in Italy (1963-2023), on the right pharmaceutical industry rankings over the total national exports*

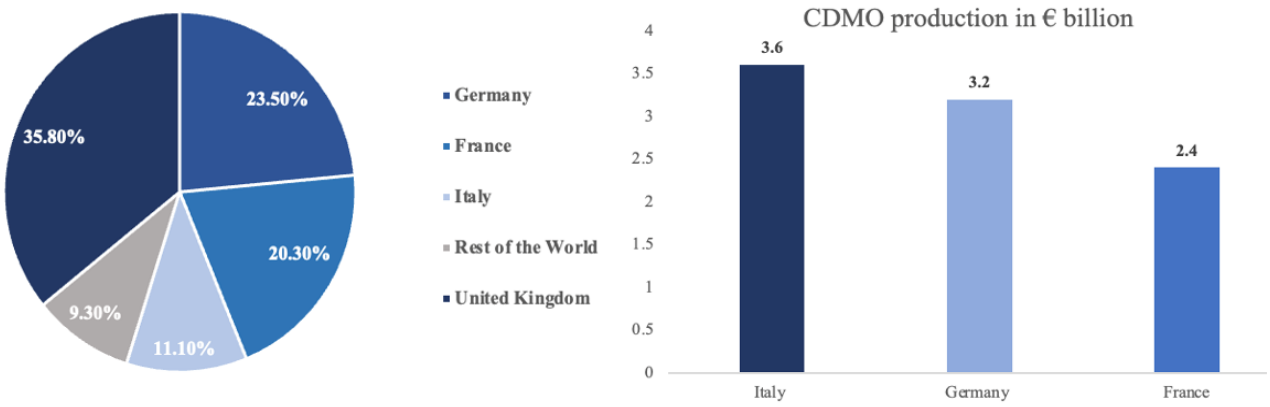


Source: FarmIndustria. 2024

Moreover, Italian pharma sector plays a crucial role in the European market, according to Exhibit 2.22, in 2023, Italy holds 11.1% of the European pharmaceutical market, ranking third after Germany (23.5%) and France (20.1%). In addition, Italy is the European leader in the CMDO (Contract Development and Manufacturing Organization) market, achieving €3.6 billion in production value, further proving the strength of the sector.[108]

[108] MarketLine Industry Profile. September 2024. Italian Pharmaceuticals.

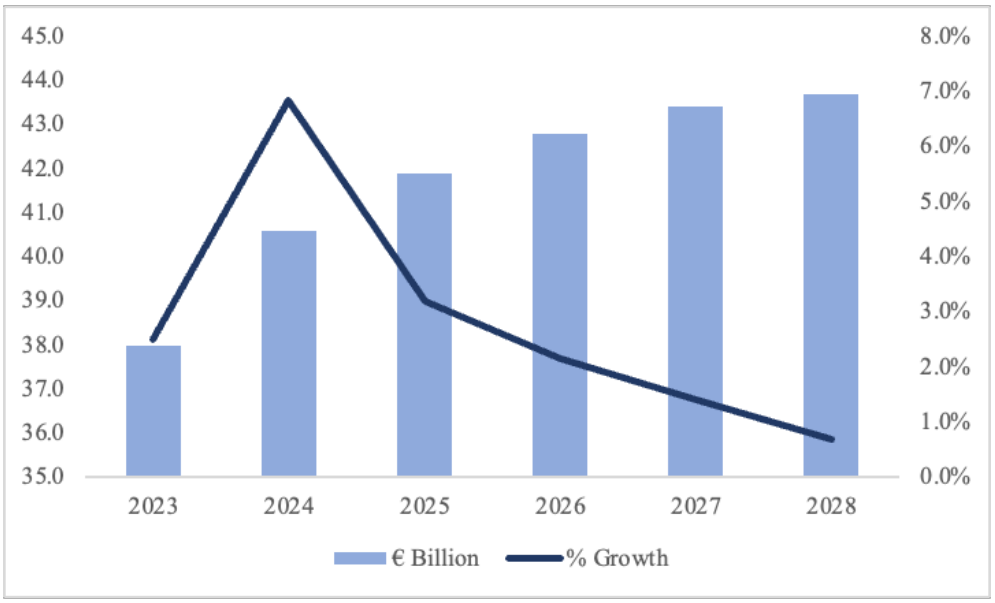
Exhibit 2.22 *- On the left, Market Shares among countries in EU (2023), on the right, CDMO production among the top 3 countries for CDMO production in EU.*



Sources: Elaborations based on MarketLine and FarmIndustria. 2024.

The Italian pharmaceutical market is projected to experience sustained growth during the 2023-2028 period, realizing an expected compounded annual growth of 2.6% with market growth expected to slow down from 2027 onward, reaching a total market value as of 2028 of $ 43.7 billion, as shown in Exhibit 2.23. Investments in online platforms, new source of technology for medical treatments accompanied by a sustained demand for chronic disease drugs due to aging population, will represent the main drivers for growth.

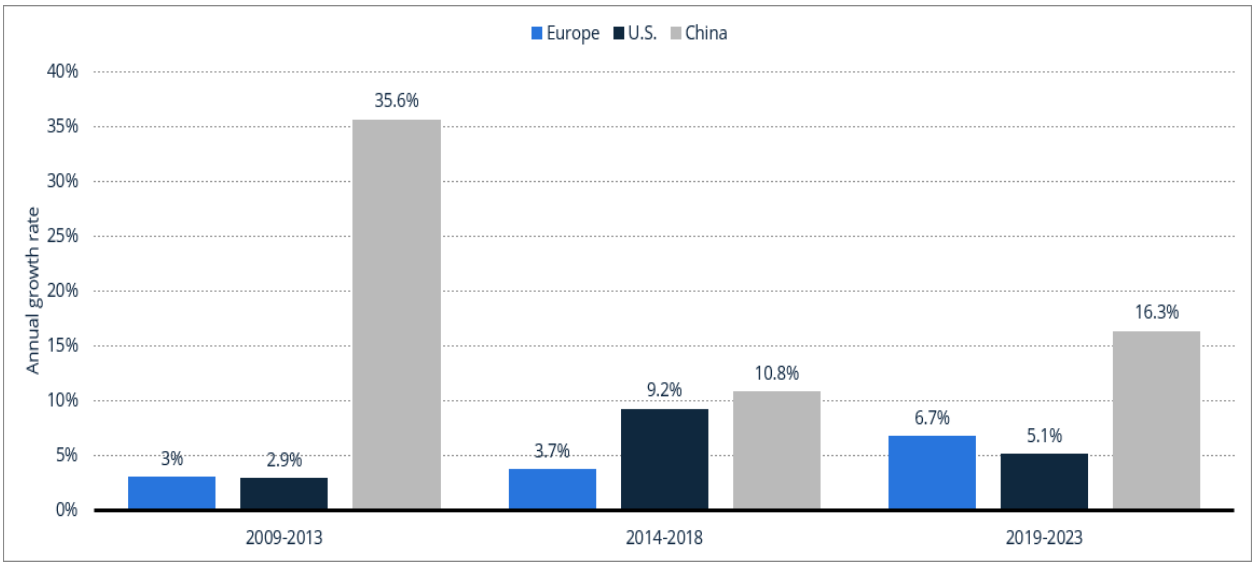
Exhibit 2.23 *- Forecasted Italian Pharmaceutical Market size (2023-2028).*



Source: MarketLine. 2024.

In parallel, the global biotechnology market achieved healthy growth within the 2018-2023 period, reaching a 10% compounded annual growth rate, driven by the surge in investment for R&D and specifically by the success in development stages of Covid-19 related medications and medical devices. Exhibit 2.24 highlights the consistent growth in R&D investments among biopharmaceutical companies for Europe and U.S. while China has demonstrated a higher growth in R&D investments.

Exhibit 2.24 *- CAGR of R&D investments in the life sciences sector*



Source: Statista. 2024.

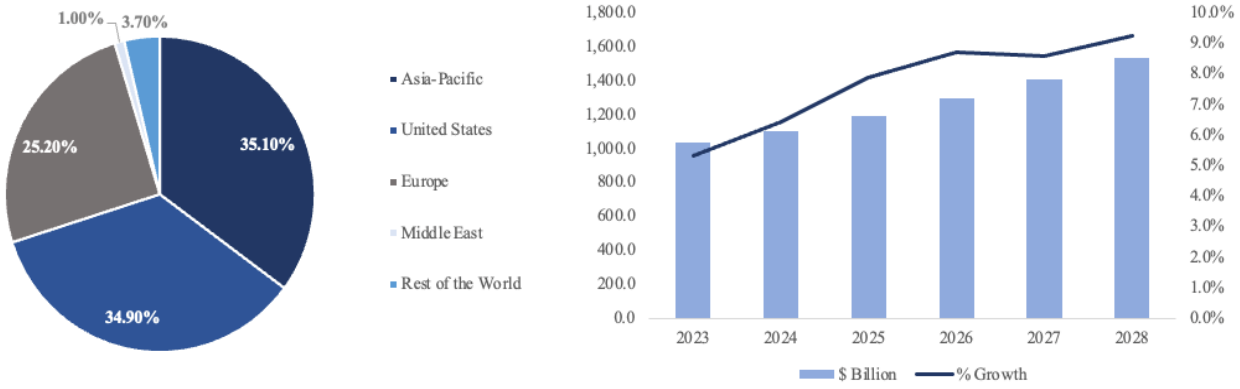
The U.S. registered a CAGR of 5.1% in the 2019-2023 period, down slightly from 2014-2018, in the while Europe and China expanded their investments recording a CAGR of 6.7 percent and 16.3 percent for the same period, respectively. As result, Asia-Pacifc biotechnology market grew between 2018-2023 at a compounded annual growth rate of 10.5%, whereas U.S. proved a stronger growth with a CAGR of 12.7% for the same period. European market on the other hand, registered an 8% CAGR for the same period strengthened by surge in R&D investments in the hope of discovering innovative therapies: for instance, in 2023 in Germany, Boehringer Ingelheim opened its new Biologicals Development Centre with financing totaling € 350 million[109].

As shown in Exhibit 2.25, the intensity in R&D investments across countries reflects in global market share structure. As of 2023, Asia-Pacific holds 35.1% of the global market share, followed by the United States, holding 34.9% of the market share, and by Europe which holds 25.2% of the global market share. In addition, the global market is forecasted to grow for the period of 2023-

[109] MarketLine Industry Profile. 2024. Global Biotechnology.

2028 to grow at a compounded annual growth rate of 8.2%, reaching a market value of $1,536 billion, driven by increased demand for clinical treatments for diabetes and weight management (GLC-1s).[110]

Exhibit 2.25 *- On the left, regional breakdown of global Biotechnology Market, on the right market forecasts of the global biotechnology market (2023-2028).*

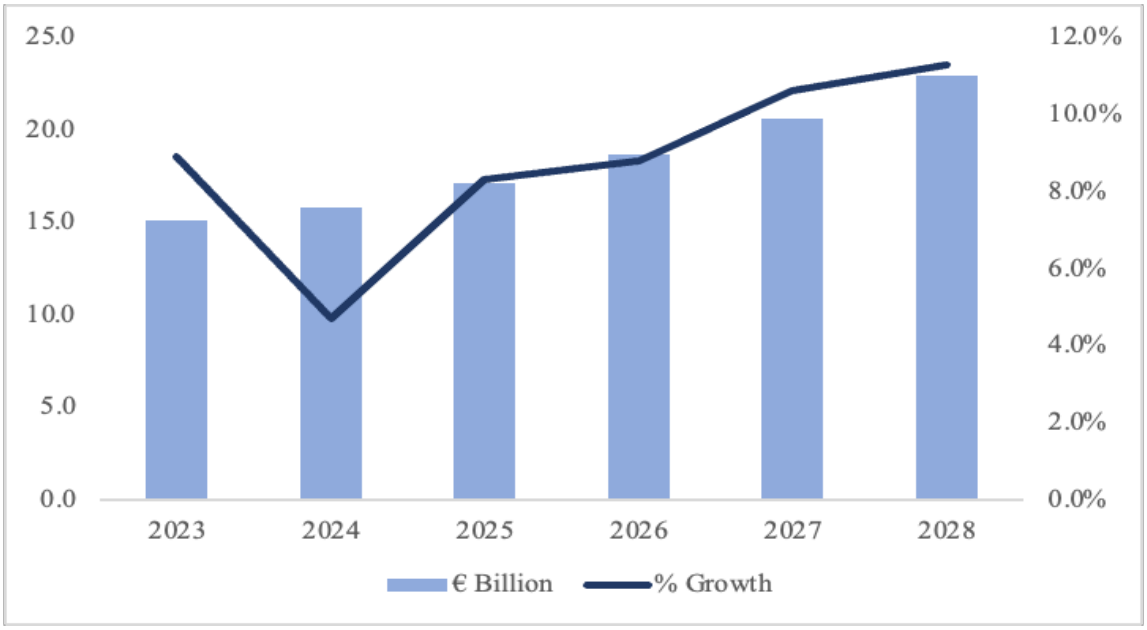


Source: MarketLine. 2024

The biotechnology market accounts for 11% of Italy's GDP[111], it holds a 6.2% of the European Market, ranking third for market share in Europe after United Kingdom (55%) and Germany (22.4%).[112] As shown in Exhibit 2.26, the Italian biotechnology market is expected to grow from 2023 to 2028 at a compounded annual growth rate of 8.7%, with an acceleration between 2027 and 2028. The Italian market is expected to expand thanks to the granular Venture Capital activity and diffuse start-up acceleration programs such as BioInItaly, Meet in Italy for Life Sciences and Bioupper.[113]

[110] Ibid.
[111] BBC. 2024. Italy's biotech, changing the way we treat and diagnose.
[112] MarketLine Industry Profile. 2024. Biotechnology in Italy.
[113] BBC. 2024. Italy's biotech, changing the way we treat and diagnose.

Exhibit 2.26 – *Italian Biotechnology Market forecast*



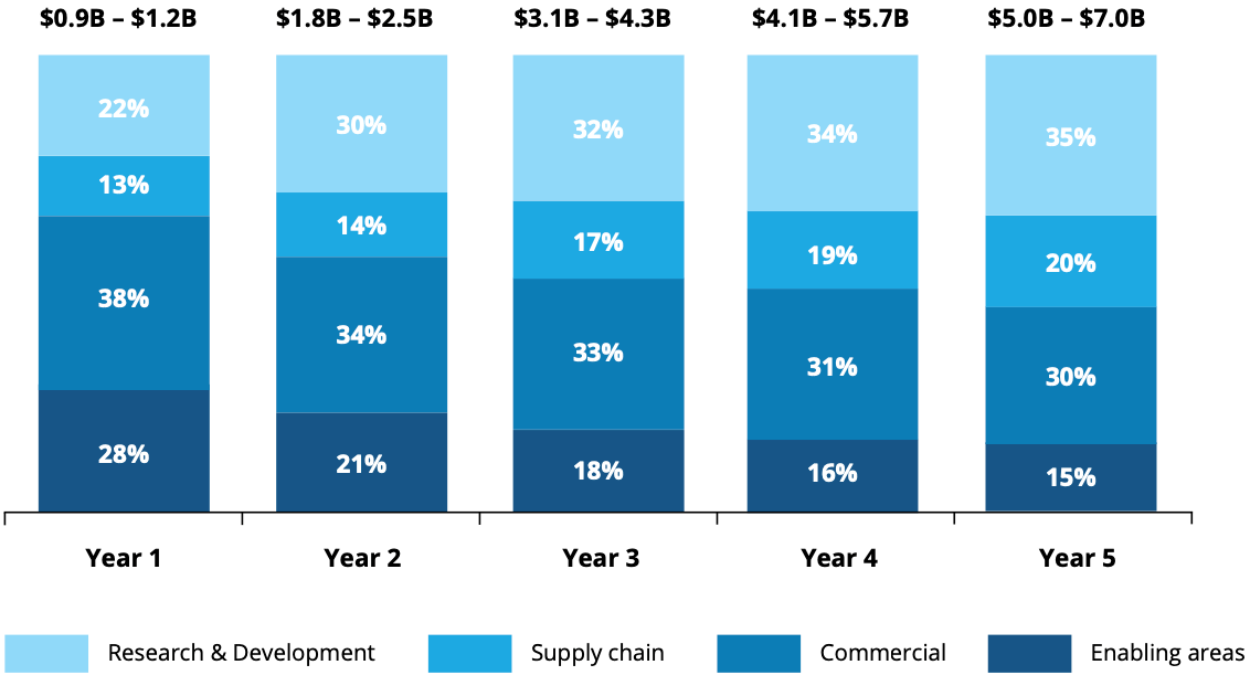
Source: MarketLine. 2024.

The expected market growth accounts also for the potential technological innovations to be introduced within the R&D and production pipelines of biopharmaceutical companies. The most groundbreaking innovation which potentially could revolutionize the value chain of the life sciences industry is the application of Generative Artificial Intelligence (Gen AI).

Deloitte estimates that life sciences company are on the verge to get access to $5-7 billion dollars of value from the usage of Artificial Intelligence, with 90% of this value stemming from the application of AI over the next 5 years in R&D, manufacturing and supply chain, and commercial activities[114]. Exhibit 2.27 reports the results of the case study carried out by Deloitte based on the application of AI on 10 companies' business operations averaging annual revenues between $ 65-75 billion.

[114] Deloitte. 2024. Realizing Transformative Value from AI & Generative Ai in Life Sciences.

Exhibit 2.27 *– Average 5-Year value accretion schedule of AI impct (percentage of value realized).*



Source: Deloitte. 2024.

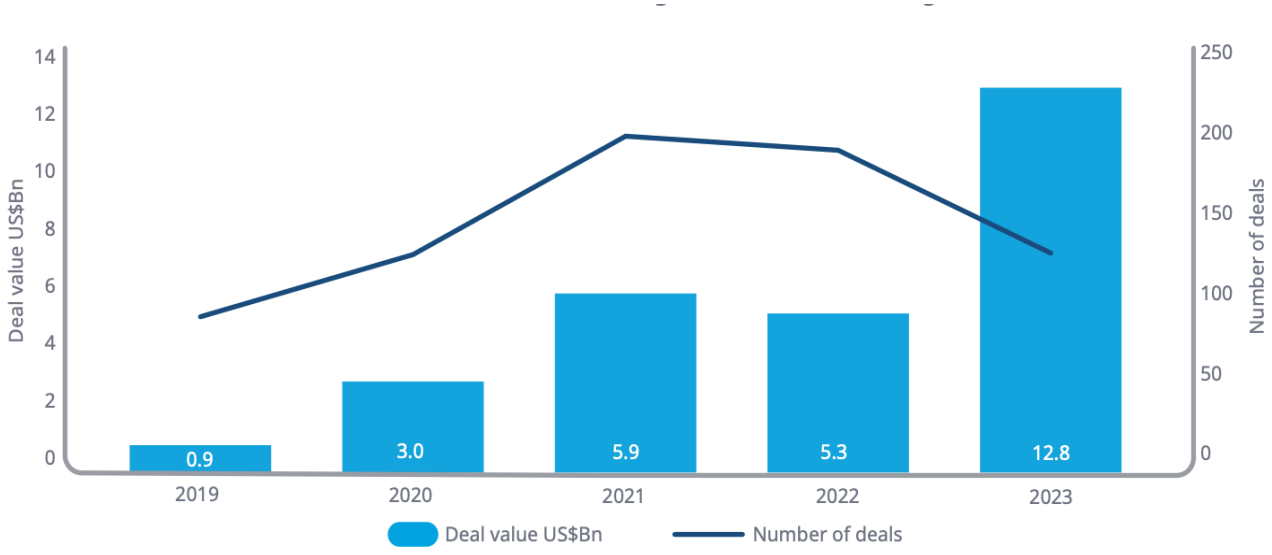
Application of AI in the Research and Development process can unleash a great part of the potential, ranging from 30% to 45% of the total expected added value, with 60% of the value generated attributable to revenue uplift and 40% traceable to cost reductions[115]. AI can be exploited in R&D to extract scientific knowledge, design drug-vector and optimize large molecule, optimize trials and portfolio, select indication for asset strategy and for in silico compound screening, which can boost to 2.5 times the performance of chemical compound activity models and 4 times the time for lead identification.[116] In addition, AI if applied in manufacturing and supply chain operations, can unleash 15-25% of the potential value, with 90% of it stemming from cost reduction. AI is thereby used as virtual assistant for manufacturing, reducing production cycle time, and for real-time inventory optimization: Sanofi for instance implemented AI algorithms to optimize production scheduling, increasing by 15% in throughput and reducing by 30% the production time.[117] Commercial applications of AI can tap in the 25-35% of the expected added

[115] Ibid.
[116] McKinsey & Company. January 2024. Generative AI in the pharmaceutical industry: Moving from hype to reality.
[117] Singh R. The impact of Artificial Intelligence in Life Sciences Manufacturing: History, Applications and Future Prospects. CXOtoday.com.

value, with 45% of cost reduction thanks to marketing content creation and medical and legal review assistance, and with 55% of revenue uplift thanks to patient experience optimization and customer enablement copilot.[118] Finally the last area of application found to have beneficial effect are various enabling areas, with 95% cost reduction thanks to reduction in software development life cycle and in public relations expenses.[119]

Biopharmaceutical companies are raising severely the investments in R&D projects based on Artificial intelligence and Machine Learning. As shown in Exhibit 2.28, in the last year, the pharmaceutical industry has invested $ 12.8 billion in deals with artificial intelligence, with overall investment value increasing by more than 141.5% with respect to 2022.

Exhibit 2.28 *- Number and value of deals with artificial intelligence, machine learning, informatics, 2019–2023*



Source: IQVIA. 2024.

This data indicate that the industry is on the verge of a revolutionary change, with AI potentially catalyzing exponential growth, as its applications to research, thanks to enhanced drug formulation, and its applications to patients' treatment, thanks to personalized medicine, could propel the life sciences industry to new heights of growth.

[118] McKinsey & Company. (2024). Generative AI in the pharmaceutical industry: Moving from hype to reality.
[119] Deloitte. 2024. Realizing Transformative Value from AI & Generative Ai in Life Sciences.

2.3 The role of Intellectual Property Rights in the Life Sciences Sector

Intellectual property rights (IPRs) are one of the main value drivers of the life sciences sector, as they constitute key assets to protect inventions and to maintain the cash generating ability of biopharmaceutical companies. IPRs in the Life Sciences sector assume multiple forms spanning from patents to trade secrets passing by copyrights and trademarks. These legal instruments can spur innovation, foster profitability, attract potential funding, and finally provide a risk management tool, as they prevent infringements from other incumbents or overriding of IPRs pertaining to other firms. The legal framework arising from IPRs thus creates the ground in which Life Sciences players tailor their business strategies and drive innovation. This section discusses the peculiarities of intellectual property rights in the life sciences, and their role as means to fuel R&D investments, firms' profitability, and innovation.

2.3.1 Setting the stage: the role of R&D in the Life Sciences Sector

The research and development process is centered at the heart of the Life Sciences industry, constituting the main driver of the value chain of pharmaceutical and biotechnological products and medical technologies. The business model of biopharmaceutical companies relies on developing new molecules capable of providing active ingredients for treating the complexities of living organisms, which are then commercialized while ensuring profitability. Research and development (R&D) serve as both the catalyst and the foundation of the life sciences industry's value chain. Consequently, the majority of capital expenditures by biopharmaceutical companies are directed towards R&D processes, not only to discover new drugs but also to ensure their marketability by obtaining regulatory approvals.

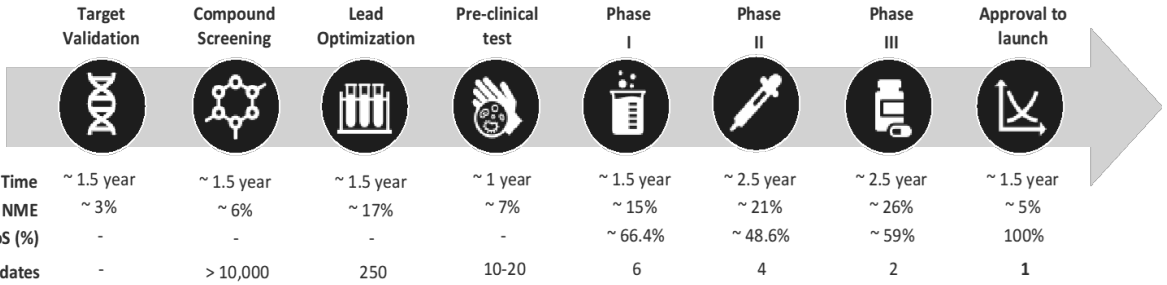
The R&D process for a new drug is both time-intensive and resource-heavy, characterized by significant risks of failure across its multiple stages. Exhibit 2.29 depicts the process of drug discovery and development, and the failure rate at each step.

The drug discovery and development process take around twelve to fifteen years from the discovery of the single therapeutically useful molecule until the new drug will be marketed[120]. The process starts with the validation of the target, which lasts around 1.5 years, through which

[120] Deore, A B., Dhumane, J R, Wagh, R., & Sonawane, R (2019). The Stages of Drug Discovery and Development Process. Asian Journal of Pharmaceutical Research and Development, 7(6), 62-67.

researchers, using biotechnological formulations, certify the molecular target (e.g., a protein) and demonstrate its functional role in a specific disease phenotype[121].

Exhibit 2.29 *– Drug development process and probability of success at each stage*



	Target Validation	Compound Screening	Lead Optimization	Pre-clinical test	Phase I	Phase II	Phase III	Approval to launch
Cycle Time	~ 1.5 year	~ 1.5 year	~ 1.5 year	~ 1 year	~ 1.5 year	~ 2.5 year	~ 2.5 year	~ 1.5 year
Cost per NME	~ 3%	~ 6%	~ 17%	~ 7%	~ 15%	~ 21%	~ 26%	~ 5%
PoS (%)	-	-	-	-	~ 66.4%	~ 48.6%	~ 59%	100%
N. Candidates	-	> 10,000	250	10-20	6	4	2	**1**

Source: Duxin Sun, Wei Gao, Hongxiang Hu, Simon Zhou (2022).

Subsequently the 10,000 candidates arising from the validation are screened through High Throughput Screenings in order to reach 250 potential candidates. Afterwards, in the lead optimization phase, candidates are reduced to 10-20 molecules in about 1.5 years. In this phase, which accounts for 17 percent of the total cost, crucial properties such as solubility, permeability, pharmacokinetics (ADME), and toxicity are studied through in vitro analysis. This is followed by preclinical testing, which lasts about a year and accounts for 7% of the cost. Here, pharmacokinetics and safety properties are evaluated to further narrow down the candidates to about 6 molecules.

Subsequently, these molecules undergo clinical tests, which are composed by three different steps that account cumulatively for 62% of the development costs. Phase I, which lasts 1.5 years and costs 15% of the total, researchers test the safety and tolerability of the drug on a small number of volunteers, in most cases 20 to 80 healthy volunteers, with a 66.4% probability of success. Candidates are reduced to about 4, who move on to Phase II, lasting about 2.5 years (21% of the total R&D cost), where efficacy and dosing are analyzed with a 48.6% probability of success. Promising drugs finally move on to Phase III, which lasts on average 2.5 years, accounting for 26 percent of the total cost, here the final drug will be selected with a 59% probability.

Finally, the drug goes through the approval and launch phase, which takes about 1.5 years and accounts for 5 percent of the costs. At this stage, candidates are evaluated by regulatory authorities, such as FDA in the United States, for marketing approval[122].

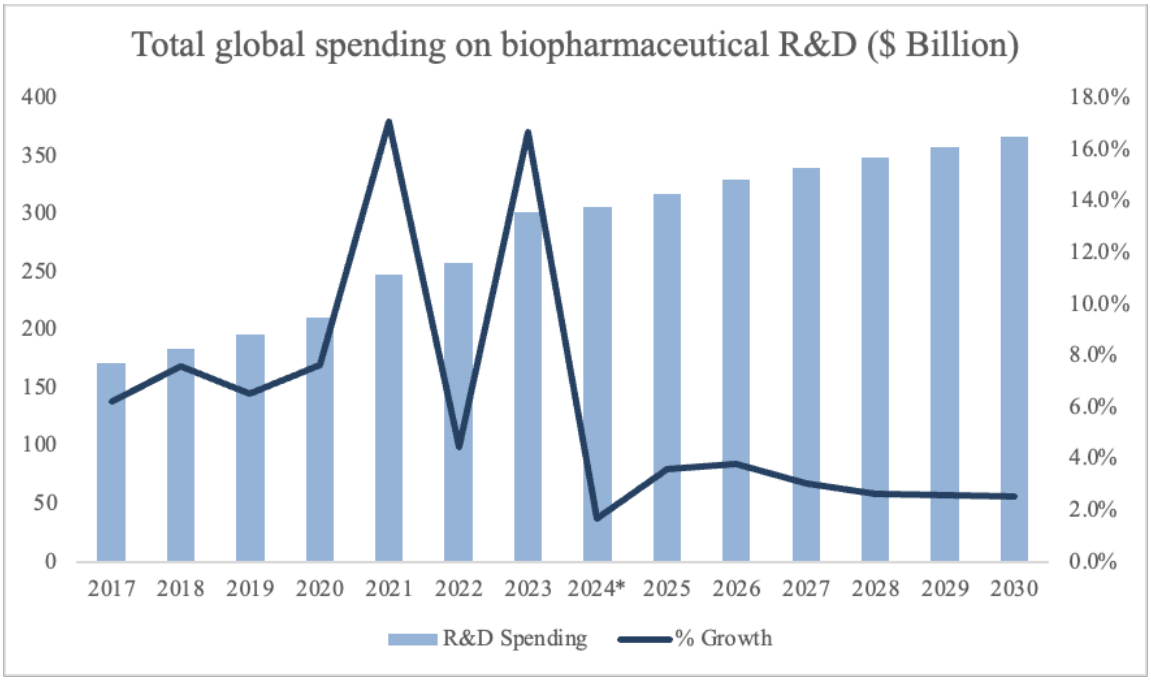
[121] Ibid.

[122] Duxin Sun, Wei Gao, Hongxiang Hu, Simon Zhou (2022). Why 90% of clinical drug development fails and how to improve it?. Acta Pharmaceutica Sinica B. Volume 12, Issue 7, 3049-3062.

The drug development and discovery process requires heavy investments for research and clinical trials, with an average R&D cost for efficacious drugs ranging from $ 1 billion to $ 2 billion.[123] The intensive capital expenditure reflects entirely the multiple experiments, as only one out of 5,000-10,000 compounds that enter development pipeline attains approval.[124] Moreover, the R&D costs reflect the failures embedded in the process: 90% of potential effective drugs fail during the phases of clinical trials and drug approval, with almost half of the failures being caused by lack of clinical efficacy traceable to the selection of the lead drug candidate[125] .

Due to the length of the process and its inherent risks, research and development in biopharmaceutical companies require high volume of investments, with higher competition driving further up R&D expenditure overtime. As depicted in Exhibit 2.30, the global biopharmaceutical R&D expenditures surged from 2017 to 2024, growing at a compounded annual growth rate of 8.7%, heavily impacted by the rapid expenditure for the Covid-19 vaccine race, and yet global R&D expenditures from 2024 to 2030 are expected to continue their growth trajectory, growing at a more stable pace, with an expected CAGR of 3.0%, thereby reaching $ 366 billion in 2030.

Exhibit 2.30 *– Total global spending on biopharmaceutical R&D*



Source: Statista. 2024.

[123] Hinkinson IV, Madej B, Stahlberg EA (2020). Accellerating therapeutics for opportunities in medicine: a paradigm shift in drug discovery. Front Pharmacol.
[124] Deore, A B., Dhumane, J R, Wagh, R., & Sonawane, R (2019). The Stages of Drug Discovery and Development Process. Asian Journal of Pharmaceutical Research and Development, 7(6), 62-67.
[125] Duxin Sun, Wei Gao, Hongxiang Hu, Simon Zhou (2022). Why 90% of clinical drug development fails and how to improve it?. Acta Pharmaceutica Sinica B. Volume 12, Issue 7, 3049-3062.

Intellectual property rights play a crucial role in protecting biopharmaceutical investments in research and development processes. As competition in the market heats up biopharma companies need to prevent their inventions to be easily replicated by other incumbents, as the latter could access the invention without bearing any R&D costs. Therefore, IP rights can establish a legal entrenchment thanks to which the biopharmaceutical inventors are able to exert the exclusive rights to their invention *erga omnes* within a specific timeframe, avoiding their capital expenditures to be vanished.

2.3.2 Patents as source of competitive advantage

Given the significant resources required for the research and development of new drugs, patents represent the most effective legal mechanism to ensure sufficient returns on investment. Patents are underpinned by the principle of *ius excludendi*, granting owners negative rights that allow them to prevent others from using their invention. This confers a 20-year monopoly period during which biopharmaceutical companies benefit from market exclusivity and the ability to charge a premium price for new drugs. Consequently, patents provide a competitive advantage to their holders, creating entry barriers that other market players must respect until the patent expires. After expiration, other competitors enter the market with biosimilar or generic drugs, initiating a process known as *generic competition*. Empirical evidence shows that the entry of three competitors offering generic drugs can reduce prices by 20%, while the entry of ten competitors can reduce prices by 80% compared to the pre-generic period.

The legal protections and applicability requirements for intellectual property rights are closely tied to the jurisdiction where they originate. The scope and enforcement of patent rights are stronger in jurisdictions with a higher number of filings. In the United States, Title 35 of the U.S. Code governs the scope and applicability of patents, outlining three primary categories.

i. *Utility Patents*, which grant the patentee the right to prevent unauthorized making, using, selling, or importing of their "useful invention," covering useful processes, machines, articles of manufacture, or compositions of matter.
ii. *Design Patents*, focusing on the visual aspects of inventions, such as shape, pattern, or configuration.

iii. *Plant Patents*, protecting inventions related to distinct varieties of asexually reproduced plants.

Most patents in the life sciences sector fall under utility patents, as these align more closely with the needs of biopharmaceutical companies filing for protection. Within this categorization, various types of claims can specify the extent to which a patent grants exclusive rights, detailing the specific object covered by the patent. U.S. jurisdiction includes substance claims, which protect the invention of a drug or therapeutic molecule, granting the patentee a legal monopoly for the standard 20-year period. Additionally, formulation claims qualify for patent protection and safeguard the biochemical formula of the molecule, described as the "unique combination of the active pharmaceutical ingredient with excipients that make up the dosage form administered to the patient." Such claims are patentable if they meet the criteria of novelty (Section 102 of the U.S. Code), non-obviousness (Section 103), and specification (Section 112).

However, global patent frameworks are not harmonized. Some countries recognize patentability for pharmaceutical products, production processes, treatment protocols, dosage regimens, drug use in treating specific diseases, packaging and delivery mechanisms, and even drug metabolites generated in the body during treatment. In Europe, the European Patent Office (EPO) provides exclusionary criteria for patentability, contrasting with the U.S. approach, which defines what is patentable. Article 54 of the European Patent Convention (EPC) outlines the first general criterion for patent eligibility—novelty—stating that the molecule's property or active principle must not be part of the prior art. Article 56 introduces the concept of an inventive step, akin to U.S. non-obviousness, ensuring that the molecule's active principle would not have been obvious to a person skilled in the art based on prior knowledge. If the innovation stems from obvious modifications, it does not qualify as inventive.

Article 57 stipulates the requirement of industrial applicability, asserting that the new active principle must be convertible into a commercial formulation or industrial product. Finally, Article 53 of the EPC states that inventions must comply with "*ordre public"* and ethical standards broadly accepted by society, prohibiting patents for human cloning or environmentally harmful practices: for instance, treatments involving human stem cells are unpatentable due to the use of human embryos. The EPC (European Patent Convention) also provides exclusions from patentability under European law. Article 52 prohibits the patenting of claims related to new discoveries, scientific theories, and mathematical methods. This means that in the life sciences

sector, if companies identify a new molecule, such a discovery in itself does not meet the criteria for patentability. However, if a biopharmaceutical company demonstrates the application of the molecule by defining the impact of its active ingredient on a specific human biological function, thereby establishing its potential as a treatment for diseases, this knowledge qualifies as an invention and is therefore patentable. For instance, if the originator proves that a known molecule or compound can treat a metabolic disease, it becomes an invention as it meets the criteria of novelty, inventive step, and industrial applicability (e.g., the creation of a drug to treat the metabolic condition). Nonetheless, there are exceptions to this definition. If a company identifies a property of a known compound in a known application, it is considered a discovery, not an invention. For example, discovering that aspirin inhibits specific enzymes would be a discovery, as it relates to the natural functioning of an existing molecule. However, proving that aspirin can prevent heart attacks transforms it into an invention.

Article 53 excludes plant and animal varieties and biological processes for producing animals and plants from patentability—processes like plant crossing or selection methods cannot be patented. However, microbiological processes, such as genetic modification of unicellular algae, are patentable according to the EPO. Further exclusionary screens under the EPO relevant to the life sciences industry include therapeutic and surgical methods applied to the human or animal body and diagnostic methods used on the body. The rationale for this exclusion is to ensure that treatments for human health remain free of legal protection, promoting broader access. The integration of the European Directive on Biotechnology has expanded patentability criteria to include genetic sequences, which have been pivotal for innovation in the biopharmaceutical sector. These genetic patents underpin many advancements in modern medicine, particularly in personalized treatments and biologics. These criteria are essential during regulatory approvals and ensure that patents remain valid and defensible in litigation.

The patent framework within the biopharmaceutical sector is not consistent across global jurisdictions. However, the key to understanding this legal institution lies in the regulator's intention to drive innovation. By making patent details public, further inventors can leverage this information to accelerate scientific progress. Regulators are willing to grant legal monopolies for patented pharmaceutical products for a 20-year period. This allows inventors to recoup their investments and enjoy increased profit margins during the patent's lifespan, in exchange for disclosing all technical information about the product, thereby enriching the scientific knowledge base. Strict requirements and extensive regulatory reviews during the approval phase ensure that

these contributions to scientific advancement justify, though not necessarily on ethical grounds, the right of the originator to impose monopolistic pricing on consumers and national healthcare systems. Over time, intellectual property rights, particularly patents, have spurred scientific progress by fostering an innovation ecosystem, including multiple players and highlights the growing convergence within the life sciences sector. This ecosystem is evident in the drug research and development (R&D) pipeline, where academia, biotech startups, big pharma, and venture capital funds collaborate to bring new drugs to market. Academia plays a crucial role in the initial phases of research and discovery within the R&D pipeline.

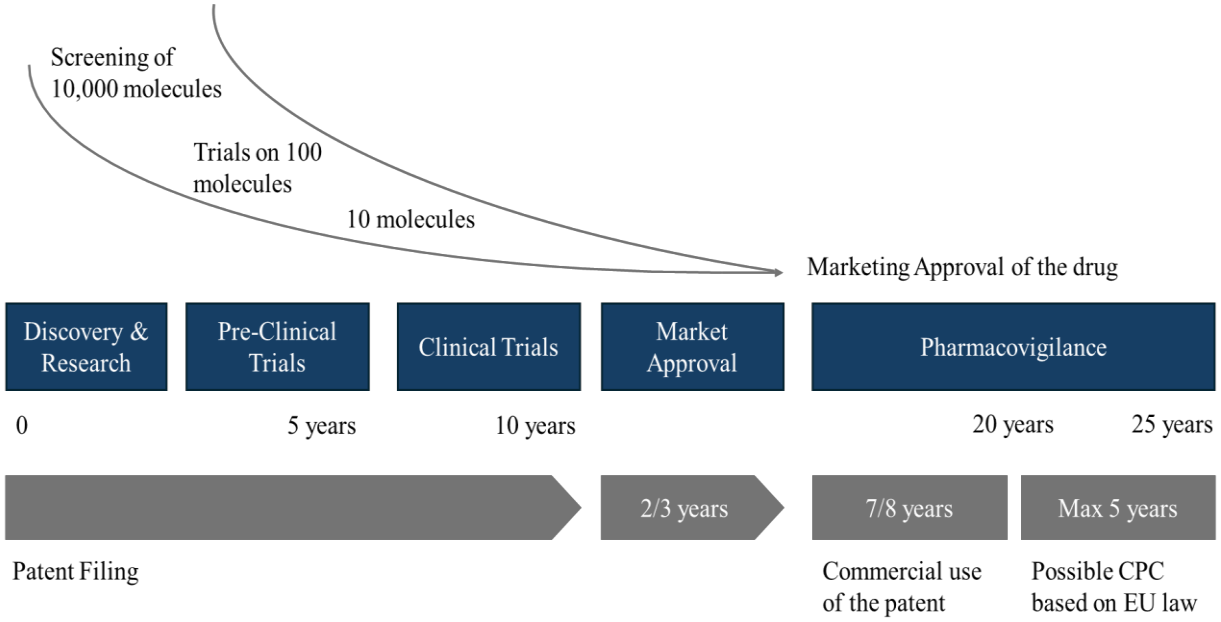
Universities, often constrained by limited funding, must find ways to attract investments to advance drug development. Intellectual Property Rights (IPRs), particularly patents, are pivotal in this process. Patents serve as valuable assets that universities can leverage to support their technological advancements. After identifying the active principle of a molecule, research groups, often assisted by Technology Transfer Offices, can patent their invention. Once a patent is granted, universities can choose between two main strategies: establishing a university spinout or entering into licensing agreements with larger pharmaceutical companies. In the case of spinouts, the patents form the foundation for creating new entities focused on drug development and commercialization. These spinouts require seed investments, often sourced from venture capital funds. The legal protections and potential exclusivity provided by patents make these high-risk, high-reward projects more attractive to investors. This funding is critical, especially for conducting clinical trials, which are resource-intensive and constitute the most significant R&D expenses. Alternatively, universities may opt for licensing agreements, transferring patented technologies to established pharmaceutical companies that have the resources and expertise to bring these innovations to market. This approach allows academic institutions to benefit financially while enabling the broader application of their discoveries. Patents not only attract investment but also ensure legal safeguards during technology transfer, reducing the risk of information leakage and fostering collaboration within the life sciences sector. These protections make IPRs a cornerstone of the biopharmaceutical innovation ecosystem, driving both the financial sustainability of research institutions and the overall advancement of scientific discovery.

Due to the intense competition in the market, biopharmaceutical companies file patents early in the research phase to protect their inventions from competitors and mitigate risks of premature disclosure that may arise from increasing collaborations between industry and academia. Small molecules offering a specific active ingredient eligible for patent protection are easily replicable.

In the absence of patents, competitors could develop biosimilars at a fraction of the original research and development costs, undermining the first-mover advantages of the originator. Patents act as a robust deterrent against duplication risks because infringement lawsuits impose significant penalties on violators. Studies indicate that alleged infringers typically face an average drop of 0.5% in stock prices when sued. Additionally, the financial burden of damages can be substantial, creating economic distress for infringers. A pertinent example is the case of Idenix Pharmaceuticals LLC v. Gilead Sciences (2016), where a Delaware jury ruled that Gilead had infringed Idenix's patent 7,608,597 and awarded damages of $2.54 billion. However, this decision was overturned in 2020 by the U.S. Supreme Court due to lack of enablement, illustrating the critical role of robust patent claims in sustaining legal protections.

The R&D process is highly time-consuming, further extended by the regulatory review required for the commercialization of a pharmaceutical product. Exhibit 2.31 illustrates the development process of a new drug, highlighting the subsequent marketability period alongside the protection period provided by the patent.

Exhibit 2.31 *– Drug development process and patent legal life*



Source: Elaboration Based on FarmIndustria

Indeed, biopharmaceutical companies file patents early in the drug development process to assert the exclusivity of their invention, effectively creating a defense mechanism against potential reproductions. Patents prove particularly useful in the event of an infringement by a competitor.

Consequently, the period for commercial exploitation of the patent—and thus the benefit derived from the legal monopoly—is often limited to an average window of 7 to 8 years. To mitigate the reduction of this benefit period caused by the lengthy clinical trial and regulatory approval processes, biopharmaceutical companies in Europe can extend the patent's validity. This is achieved through the application for a Supplementary Protection Certificate (SPC). If granted by the EUIPO, the SPC can extend the patent's validity for an additional five years, covering human or veterinary medicinal products and plant protection.

2.3.3 Managing Patent Cliff

The duration of the monopoly granted by patent rights is crucial for ensuring that the Net Present Value (NPV) of the drug development process remains positive. Companies can increase the Internal Rate of Return (IRR) of a project by artificially waiving the patent cliff through strategies collectively known as *Evergreening*. These strategies are primarily employed to extend the exclusivity rights of blockbuster drugs by securing multiple patents that protect various aspects of the same product or by patenting improved versions of existing products. Evergreening strategies can take multiple forms and often leverage different types of intellectual property rights to extend the exclusivity of patent rights.

The most common evergreening strategy is the creation of an extensive web of complementary patents or patents subsequent improvements with respect to a product patent. Biopharmaceutical companies during the lifeline of the blockbuster's patent, continue to invest heavily in its R&D, thereby optimizing the product, improving the process by incorporating new technologies, discovering new medical applications, and even changing its formulation. This strategy is commonly referred as patent thicket: as the learning curve will progress, firms will file patents based on every new innovation related to the product, thus creating multiple layers of legal fence around the blockbuster's patent[126]. Patent thickets are thus tailored based on multiple secondary patents or continuation patents which offer a limited degree of innovation, and for this reason they are the major source of patent litigation.

[126] Carrier M, Tu S. 2024. Why Pharmaceutical Patent Thickets Are Unique. Texas Intellectual Property Law Journal. Vol. 32:79, 81-87.

It is important to specify that continuation patents to this extent are not characterized by an extended expiration date compared to the parent patent, hence do not extend legally the expiration time of the parent patent; albeit by increasing the number of continuation patents claims become narrower deterring biosimilars from market entry after the patent cliff[127]. Another important strategy can be configurable in *product hopping,* the process through which the blockbuster manufacturer reformulates the drug in a way that makes the generic biosimilars non-substitutable, thereby shifting the demand towards the branded version, even employing marketing campaigns to redirect providers and doctors[128].

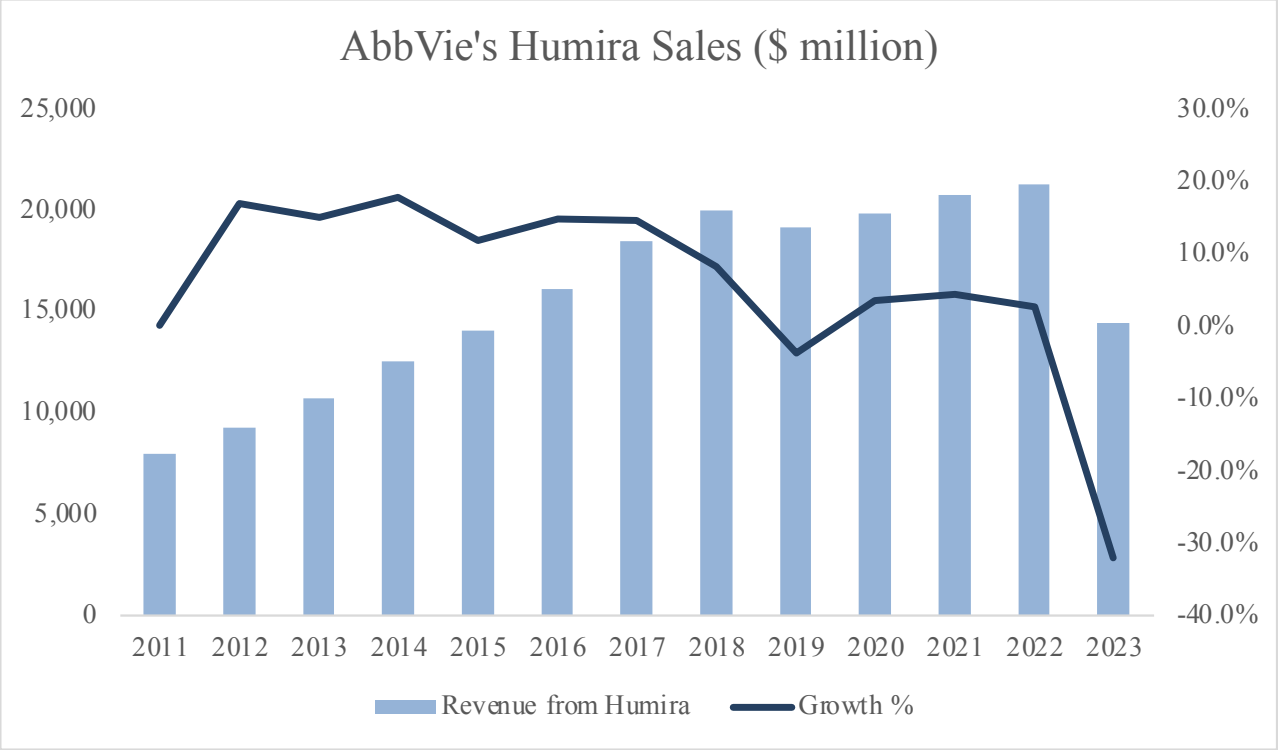
This process is based on the usage of substitute patents, through which the originator will file for a secondary patent by changing the formulation or the dosage, thereby creating sometimes stronger versions of the blockbuster drug. AbbVie provides a striking example of how evergreening strategies can extend the monopolistic period of a blockbuster drug, stretching the revenue streamline. AbbVie implemented a combination of evergreening tactics to maintain its monopoly on *Humira* (*adalimumab*), the best-selling drug for treating various diseases, including arthritis and Crohn's disease. As Humira's exclusivity period approached its expiration, which was deemed to be in 2014, AbbVie began to heavily employ patent thicket strategies by creating an extensive web of multiple secondary patents from 2013 onwards: before 2013 Abbvie filed only 11 secondary patents, while from 2013 to 2020 Abbvie filed a total of 55 continuation patents, of which more than 80% was filed after the expiration, thereby narrowing the claims and deterring potential biosimilars to be in the market[129]. In parallel, AbbVie applied product hopping by reformulating *Humira* into less painful high concentration drugs such as *Skyrizi* and *Rinvoq,* thereby shifting demand towards this new formulation and to the detriment of generic drugs[130].

As highlighted in Exhibit 2.32, Humira generated $186.6 billion of sales from 2013 to 2023, with annual revenues significantly expanding after 2013; between 2014 and 2019, annual revenues grew at a CAGR of 8.9%. This growth is unusual given that this period coincides with the expiration date of the parent patent and the start of generic competition. By leveraging this combination of patent strategies, AbbVie maximized Humira's sales, significantly increasing

[127] Ibid.
[128] Carrier M, Shadowen S. 2017. Product Hopping: A New Framework. Notre Dame Law Review. Vol. 92 (1).
[129] Carrier M, Tu S. 2024. Why Pharmaceutical Patent Thickets Are Unique. Texas Intellectual Property Law Journal. Vol. 32:79, 81-87.
[130] Gibbons J, Laber M. 2023. Humira: The First $20 Billion Drug. The American Journal of Managed Care Vol. 29.

revenue consistency and longevity while maintaining barriers to entry: a clear example of how strategic usage of patent rights can yield high returns for biopharmaceutical companies.

Exhibit 2.32 *– Humira Sales Revenues from 2011 to 2023.*



Source: Statista. 2024.

2.3.4 The role of Licensing and other Intellectual Property Rights

Patents constitute a fundamental asset to create value for biopharmaceutical companies, as the exploitation of monopoly rights arising from patent rights allow them to increase their cash flow generating ability, thereby generating extra returns on R&D investments. For this reason, this intellectual property right is a crucial object of intercompany negotiations. A patent owner can monetize their innovation through licensing agreements, allowing third parties to access to their technology, thereby developing and marketing its product. This approach eliminates the need for the patent holder to invest further in development or bear the costs of regulatory approval while generating revenue streams to recover initial research and development investments. Patent law outlines the ground through which licensing agreements are sealed, which in the majority of cases constitute the lifeblood of university spinouts' revenues.

Universities and biotech start-ups cannot afford to face clinical trials costs unless benefiting from seed funding; to this purpose they can license the patent right to bigger pharmaceutical companies entrusted with resources and competencies to bring the product to the market. On the other hand, big pharmaceutical companies often are not fully vertically integrated or do not have enough expertise to cover the initial discovery of the molecules or the biotechnological technique, thus they may enter in a licensing agreement with biotech start-up to access technology: licensing agreements can bridge the know-how and technology gap between the early phases, usually covered by small biotechnology firms, and later stages (clinical testing and commercialization) of life sciences' value chain. In addition, licensing agreements are pivotal for biopharmaceutical companies to enter new geographical markets, as the licensee has the required resources to up-scale distribution channels and it has fundamental knowledge of the local market, especially considering regulatory framework. For different biopharmaceutical companies licensing constitutes one of the main sources of revenues, as they tend to not be fully integrated. Kollmer H. & Dowling M. (2004) have found that for early-stage biotechnology companies licensing comprises the main commercialization strategy, as 76% of their revenues can be redirected to licensing contracts[131]. In parallel, also for fully integrated biotechnology companies licensing constitutes one of the main sources of revenues, licensing contributes on average to 38% of the total revenues stream.[132]

Thus, a biopharmaceutical company can opt for out-licensing the intellectual property right to guarantee return on R&D investments, instead of undertaking extra investments to set up the later regulatory approval and marketing phases. Biopharma companies can take advantage of other forms of licensing agreements than exclusive license, thereby renouncing to the exploitation of the underlying intellectual property right to grant it solely to the licensee[133]. Firms in the Life Sciences sector often engage in cross-licensing agreements thereby strategically sharing IP rights for a common strategic objective; from this framework multiple firms can enter simultaneously into a patent pool agreement, sharing among each other usually complementary patents, thus creating fertile terrain to foster innovation[134]: GlaxoSmithKline (GSK) launched in 2009 the *Open Innovation against Neglected Tropical Diseases* patent pool to facilitate access to technology and

[131] Kollmer H. Dowling M. 2004. Licensing as a commercialisation strategy for new technology-based firms. Research Policy 33, 1141-1151.
[132] Ibid.
[133] Bogers, Marcel & Bekkers, Rudi & Granstrand, Ove. 2012. Intellectual Property and Licensing Strategies in Open Collaborative Innovation. Open Innovation in Firms and Public Administrations: Technologies for Value Creation.
[134] World Intellectual Property Organization (WIPO). 2014. Patent Pools and Antitrust – a Comparative Analysis.

know-how to tackle world's most neglected tropical diseases. The combination of patents and licensing agreements is not only a source of competitive advantage for singular players but can be a promoter of scientific progress. Patent holders can issue voluntary licenses or adopt non-assert declarations[135], allowing the replication of a drug or molecule for the production of generics. This approach enhances access to scientific advancements in developing countries, addressing global health challenges. A notable example is Gilead's non-exclusive licensing agreements with seven India-based generic manufacturers to allow developing countries to access to its chronic hepatitis C treatments[136].

Licensing agreements in the Life Sciences industry are not only restrained to patent rights, but they may involve trademark, trade secrets, and copyright. While trademarks are another widespread object of licensing agreements, these rights are crucial to maintain competitive advantage of biopharmaceutical companies. Trademark rights protect any recognizable signs, words, designs, letters, numerals, colours, shape of goods and their packaging[137]. Trademark rights are therefore fundamental to safeguard a biopharmaceutical company's brand identity. Trademark can play a crucial role in maintaining market shares of a specific drug, as patients and doctors can easily recognize the medication. To this extent trademark rights can be employed in evergreening strategies. Patented drugs, as in the case of *adalimumab,* are marketed under their brand name (Humira), and not under the generic name. For this purpose, biopharma companies file the trademark of the name of the drug in order to restrain competitors from its exploitation. For blockbuster drugs that serve niche markets, the resonance of the brand name gives monopoly power to the drug even after patent cliffs: physicians may continue to prescribe the branded product even sometimes without knowing the existence of other biosimilars[138]. Moreover, trademark and designs can be used to protect the colour and the form of the capsule,[139] thereby maintaining competitive advantage even after the patent cliff, as consumers will associate the trademarked colour and shape to the drug they need for their therapy. In parallel, copyrights can be strategically exploited in drug labelling, in order to protect the domain of the printed

[135] Under a non-assert declaration, the originator agrees to not enforce patent rights against any user of the patented technology.
[136] Gilead Sciences corporate website. 2014. Chronic Hepatitis C Treatment Expansion Generic Manufacturing for Developing Countries.
[137] Art. 4 Regulation (EU) 2017/1001 on the European Union Trademark.
[138] Dutfield G. Intellectual Property Rights and the Life Science Industries. 20th Edition. 110-115.
[139] Ibid.

information accompanying the product, including labelling guidelines[140]: often creating legal disputes such as the case *SmithKline Beecham Consumer Healthcare v. Watson Pharmaceutical*[141]. Copyrights do not constitute fundamental intellectual property assets; albeit, as copyrights protect an author's creative expression of their ideas, academia usually employ them in order to protect scientific publications together with *bioinformatics* related assets[142].

Licensing agreements can also cover trade secrets, though this operation may carry out several risks for the licensor as the risk of disclosure could undermine the strategic value of this intellectual property right. Trade secrets in contrast to patent rights have indefinite life[143], and base their strategic advantage on secrecy. Different biopharmaceutical companies may rely on trade secrets to protect manufacturing processes and biologics: emblematic is the judicial case of Genentech against a former employee who stole biotech trade secrets providing them to a Taiwanese competitor. The degree of opacity of trade secrets implies hardships in assessing the real competitive advantage of trade secrets; however, we may infer the strategic importance of trade secrets by taking into consideration Coca-Cola's trade secret in determining its market dominance. As a result, trade secret protection enables companies to keep specific innovations undisclosed, particularly those that are ineligible for patent protection, such as unique biotechnological processes, safeguarding competitive advantage.

[140] Termini R. 2013. Copyright and Trademark Issues in the Pharmaceutical Industry. Generic Compliance or Brand Imitating: "Copycat or Compliance". Pennsylvania Bar Association.
[141] In 1999 SmithKline accused Watson Pharmaceutical, a generic drug manufacturer, of copyright infringement as Watson allegedly copied the wording accompanied SmithKline's drug *Paxil*.
[142] Gulati R. 2021. Role of IPR in Life Sciences industries. Journal of Science, Computing and Engineering Research. Volume 2, Issue 2.
[143] Nealey T, Daignault R. 2015. Trade Secrets in Life Science and Pharmaceutical Companies. Cold Spring Harbor Prespectives in Medicine.

Chapter III

Valuing Intangibles and Intellectual Property Rights

3.1 Valuing Intangible Assets: Principles and Practical Implications

Intangible assets frequently represent a critical factor for competitive success in a business, both in terms of profitability and in enhancing corporate image and reputation. Increasingly, when analysing company financial statements, a notable relationship emerges between intangible assets and tangible or financial assets, with intangible assets often taking precedence. This trend can be specifically appraised in the Life Sciences Sector, where intangible assets are a vital component in determining firm's value. This trend has been observed in the past as well. For instance, Smith and Parr, in the early 2000s, identified that intangible assets accounted for significant percentages of the total assets in major companies and especially for companies operating in the Life Sciences sector, such as Johnson & Johnson, amounting to 87.9% and Merck, being equal to 93.5%[144]. Sometimes, certain companies base their entire value on the set of intangible assets recorded on their balance sheet. Examples include companies that are no longer operational but own a well-known brand, or biotech start-ups that have developed a new drug and hold the license for its production and marketing but have not yet established any production facilities[145].

The growing importance of intangible assets has consequently led to the need to assess these assets, a process that must be carried out in various contexts, such as intellectual property management, impairment tests, insolvency proceedings, M&As, purchase price allocations, joint ventures and licensing agreements. In the context of intellectual property management, the valuation of intangible assets is essential for establishing performance metrics and assessing business strategies. International accounting standards, specifically as envisaged by IAS 36, require that assets must not be carried in the financial statements at more than the highest amount to be recovered through their use or sale: for this reason, through the application of intangible valuation, impairment testing ensures that the book value of the asset does not exceed the recoverable amount.

In the M&A context, the valuation of intangible assets is necessary to determine the enterprise value, and thus the equity value, of the target, as intangibles contribute to the determination of the company's cash flow generating ability. In this context, intangible assets can be broadly classified

[144] Smith G. Parr L., (2000), Valuation of Intellectual Property and Intangible Assets 131-147
[145] Vulpiani M., (2014), Special Cases of Business Valuation, 449-451.

into two categories based on their contribution to generating cash flow: those that independently generate cash flow and those that contribute to the overall cash flow of the business as a whole[146]. Independent cash generating assets have a usually finite life and can be traceable to trademarks, copyrights, and patents. These intangible assets can be defined as independent, since it is possible to isolate their value from the rest of the firm's assets, as the sole exploitation of these asset is able to generate cash flows. Independent cash-flow-generating intangible assets yield exclusive right to produce a product or provide a service, thus their value stems from the cash flows generated from these exclusive rights. On the other hand, firmwide cash-generating intangible assets are characterized by the difficulty of isolating their standalone value, as their contribution to cash flow generation is not limited to a single product or cash-generating unit (CGU) but extends across the entirety of the business activities[147]. The intangible assets that fall within this category are brand names and assembled workforce, as they entrust the firm of unique competitive advantages with respect to other incumbents. Brand names leverage customer relationship in order to decrease marketing and distribution costs, as consumers have already trust in firm's products and distribution channels are already crystalized and ultimately justify higher product pricing due to perceived product quality[148].

Moreover, within the business combinations framework, envisaged by IFRS 3, intangible asset valuation assumes a crucial role in allocating the purchase price to the target's assets, liabilities and goodwill, i.e. *purchase price allocation*. In other terms, intangible asset valuation allows the identification of the fair value of target's assets thus carrying out an effective allocation of the acquisition price after closing of the deal. An accurate purchase price allocation (PPA) increases the transparency of company financials, better reflecting the economic value of the acquired net assets. In the PPA context, an extensive intangible valuation reduces the portion of the purchase price attributable to goodwill, giving more information and specification of acquired assets which drive the company's future growth capabilities. IFRS 3 outlines, though not exhaustively, the categories of intangible assets that can be recognized and thus valued through purchase price allocation, as shown in exhibit 3.1. Provided that the requirements for asset identifiability[149] are met, intangible assets that are often object of recognition in the PPA context are: marketing-related

[146] Damodaran A, (2006), Damodaran on Valuation, 407-423.
[147] Ibid.
[148] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 341-344.
[149] According to IFRS 3 intangible asset are identifiable if they stem from contractual-legal rights or capable of being separated or divided from the acquiree and sold.

intangible assets, those which are generated from marketing efforts such as trademark and trade name; customer-related assets, assets that stem from the relationship with the customer base, such as the customer relationship; artistic assets, such as the logo and audio-visual materials; contract-related assets, all the assets which arise from contractual relationship such as franchise agreements and licensing agreements; and finally technology-related intangible assets that arise from proprietary technology such as patents and software. The residual purchase price is then allocated to goodwill, which is the difference between the consideration paid to acquire the target and the book value of its net assets.

***Exhibit 3.1**. Common categories of identifiable intangible assets that may be acquired in a business combination*

Artistic-related intangible assets

- plays, operas and ballets
- books, magazines, newspapers and other literary works
- musical works such as compositions, song lyrics and advertising jingles
- pictures and photographs
- video and audio-visual material, including films, music videos and television programmes.

Contract-based intangible assets

- advertising, construction, management, service or supply contracts
- licensing, royalty and standstill agreements
- lease agreements
- construction permits
- franchise agreements
- operating and broadcasting rights
- use rights such as drilling, water, air, mineral, timber-cutting and route authorities
- servicing contracts such as mortgage servicing contracts
- employment contracts that are beneficial contracts from the perspective of the employer because the pricing of those contracts is below the current market value.

Marketing-related intangible assets

- trademarks, trade names, service marks, collective marks and certification marks
- internet domain names
- trade dress (unique colour, shape or package design)
- non-compete agreements.

Customer-related intangible assets

- customer lists*
- order or production backlog
- customer contracts and the related customer relationships
- non-contractual customer relationships*

Technology-based intangible assets

- patented technology
- computer software and mask works
- unpatented technology*
- databases*
- trade secrets such as secret formulas, processes or recipes.

* These items are usually considered as identifiable intangible assets because they meet the separability criterion. All other items usually satisfy the contractual-legal criterion.

Source: Grant Thorton, (2003), Insights into IFRS 3.

At first glance goodwill may seem a mere plug-in variable that allows the balance sheet to balance after the combination[150], however it reflects the excess business enterprise value over the one that would be yielded if only considering the aggregated identified assets[151]. Some studies argue that

[150] Damodaran A, (2006), Damodaran on Valuation, 407-423.
[151] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 48-53.

the excess value reflects customer loyalty (Smith & Parr) and the synergies inherent in the acquisition and the integration of the target company into the acquirer's business model: Johnson & Petrone provide a measure of core goodwill as the sum of the going concern of the target[152], and the synergies created from the acquisition[153]. Notwithstanding the capacity of goodwill to generate excess earnings over time, when target's intangible assets, and specifically its intellectual property rights determining firmwide cash-generating intangibles are effectively valued, there will be no residual value to assign to goodwill. Conversely, the presence of excessive goodwill presents several risks. It may indicate that the purchase price reflects an overpayment for the acquisition, failing to accurately capture the additional value created by the transaction. Additionally, the accounting implications of excessive goodwill must be considered. Since goodwill cannot be amortized and is only subject to impairment testing, the likelihood of future impairment losses becomes significant. This also results in reduced transparency in the income statement due to the absence of amortization for intangible assets, as well as a loss of potential tax benefits for the acquiring company. Furthermore, as highlighted by Paugam et al., excessively high goodwill increases the risk of negative market reactions, primarily due to the perception that the acquisition price is inflated[154]. These factors emphasize the necessity of purchase price allocation, where the proper valuation of intangible assets takes on a central role.

Finally, for licensing agreements, the valuation of intangible assets is critical for determining their value for both the licensor and the licensee. Additionally, there are other areas where the evaluation of intangible assets plays a key role, such as in the filing of foreign patents, the payment of patent maintenance fees, intellectual property audits, inter-company transfers of intellectual property, and the securitization of intellectual property.

Regardless of the purpose, whether for accounting, technological transfer, or extraordinary transactions, the valuation of intangible assets is based on the concept of market value. International accounting standards define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the valuation date. This definition of fair value assumes the existence of a market where the interests of the buyer and seller align for the asset being assessed. As shown in Exhibit 3.2, this alignment

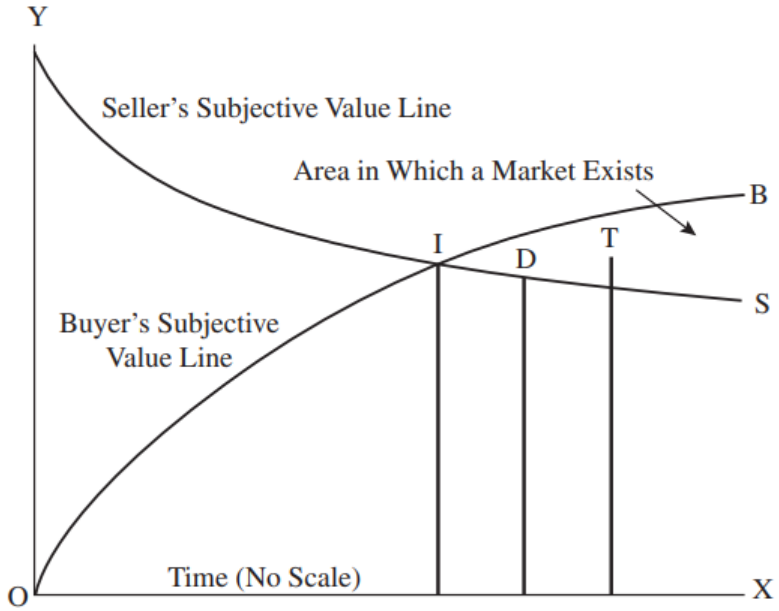
[152] According to Smith & Parr, the going concern value represents the additional value generated by a business operating as an ongoing entity compared to its value in a state of insolvency. This value can be assessed by "considering the cost incurred to do all the acquiring and organizing plus the profits lost during the process".

[153] Johnson L.T., Petrone, K.R., (1998). Is goodwill an asset?. Account. Horizons 12, 293-303.

[154] Paugam et al. (2015). Accounting for business combinations: Do purchase price allocations matter? J.Account. Public Policy. 34, 362-391.

occurs through negotiation between the two parties, effectively creating a market within the area between Curve B, representing the buyer's subjective value, and Curve S, representing the seller's subjective value.

Exhibit 3.2 *- Buyer-Seller subject value concept*



Source: Thurston H. Ross, (1933), Some Economic Aspects of Urban Land Valuation

The intersection of these subjective valuations, which are based on the extent of future benefits that will be derived from the utilization of that resource, is reached through negotiation, ultimately determines the fair value of the asset. In this context, as defined by the PIV (Italian Valuation Principles), market value requires that the parties act knowledgeably, prudently, and without undue influence or pressure[155]. To establish the fair market value of intangible assets, particularly intellectual property rights, generally accepted valuation techniques can be applied. These techniques are typically grouped into three main categories:

i. The *cost approach*, through which the fair market value of the intangible asset is derived based on the amount that would be paid currently by the entity, to replace the service capacity of that specific asset, i.e. replacement cost[156];

[155] Organismo Italiano di Valutazione, (2015), Italian Valuation Principles (PIV)
[156] Vulpiani M., (2014), Special Cases of Business Valuation, 449-451.

ii. the *market approach*, through which the fair market value of the intangible asset is estimated based on analyses of recent sales of comparable assets, or based on the asking price of comparable assets available for sale;

iii. the *income approach,* through which the fair market value of the intangible is derived based on the discounted future cash flows that an asset is expected to generate over its useful life.

The following sections provide a detailed description of the traditional methodologies, commonly referred to as generally accepted techniques used for the valuation of intangible assets, and as such intellectual property assets.

3.2 The Cost Approach

The cost approach measures the value of an intangible asset based on the principles of substitution and price equilibrium. This approach assumes that a prudent buyer would not pay an amount exceeding the cost of developing an equivalent asset, which is one that provides the same level of desirability and ensures equivalent utility through its ownership.[157]. It is also important to clarify that this approach is based on the assumption that the cost of acquiring or developing a new asset is proportional to the economic value that the asset can generate over its useful life.[158]. In fact, the cost approach takes into account the existence of future economic benefits derived from the use and the ownership of the asset under evaluation. These benefits must be sufficient in both quantity and duration to justify the cost of developing or creating the specific asset[159].It is important to specify that the methodologies within the cost method framework do not directly measure these future economic benefits. Rather, they rely on the key assumption of their existence to justify the asset's valuation, suggesting that a prudent buyer would be willing to incur the associated costs[160]. In the absence of such an assumption, any valuation judgment of the asset is foregone, and in this case, its value will be entirely anchored to its historical cost[161].The computation of historical cost is typically employed for intangibles under development, particularly when the likelihood of success for investments in the creation of the intangible asset is extremely difficult to measure. In other words, these development costs are still far removed from market dynamics, making it nearly impossible to estimate demand and sales for the associated product. An example of this can be found in the early discovery costs of molecules within the life sciences sector[162].

Furthermore, the future economic benefits of owning such an asset, on which the cost method is based, must consider depreciation and obsolescence affecting the asset in question. This is necessary in order to determine the maximum value of an asset for a potential buyer[163]. Depreciation is an intrinsic characteristic of assets with repeated utility; it reflects the reduction in value and, consequently, the desirability of the asset under current market conditions due to the passage of time. The depreciation of an asset is essentially driven by three main factors: physical wear and tear, advancing technology, and changes in economic conditions. While economic conditions impact the asset’s value through changes in consumer demand, physical wear and tear

[157] Ibid.
[158] Smith G. Parr L., (2000), Valuation of Intellectual Property and Intangible Assets, 131-147, 3rd ed.
[159] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 48-53, 5th ed.
[160] Ibid.
[161] Guatri L. Bini M.
[162] Ibid.
[163] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457

reduces its operating performance in terms of speed and accuracy, compared to new equivalent assets available on the market. Intangible assets are not characterized by physical wear and tear, however they are subject to depreciation Conceived as a loss of value due to technological advancement: the technological state of the art leads to the presence of more efficient, faster and less expensive equivalent assets in the market. As a result, the presence of more innovative comparable assets leads to the obsolescence of the intangible, as it may no longer generate similar economic benefits and competitive advantage compared to other assets in the market[164]. In parallel, the obsolescence of the intangible, just as in the case of tangible assets, is impacted by the economic conditions of the business in which it is devoted: the integrity of the asset's value is preserved as long as it yields a sufficient rate of return, which ultimately can be impacted by the market trends over time.

Therefore, under this framework, the cost approach is based on the estimation of the costs of the asset, which in turn needs to offset the negative impacts on asset's value caused by depreciation. According to Reilly & Schweihs, the cost approach is based on the current identification of two distinct costs: cost of reproduction new (CRN) and cost of replacement (COR). The former refers to the cost that would be incurred to produce a new replica of the asset being analysed, while the latter refers to the cost of acquiring an asset of equivalent utility in the market. Therefore, the difference between the two is that the cost of reproduction tends to be lower, as it reflects the benefits of advancements in the state of the art: in this sense, the cost of reproduction new incorporates obsolescence[165].

Smith & Parr, to determine the reproduction cost of a new replica of an asset, propose historical cost trending as a primary methodology. The approach involves restating the past costs necessary to reproduce the asset in terms of current purchasing power. Companies track the costs incurred over the years for the development of specific intangible assets particularly in the case of internally generated software. Development costs incurred over time are evaluated to determine whether they would still have been incurred using currently available development methods or tools. Once this adjustment is made, historical development costs are translated into current currency values. To achieve this, the historical cost trending methodology relies on price indices capable of capturing price differences, such as variations in labor costs. The sum of these adjusted costs, reflecting current purchasing power, determines the reproduction cost of the asset in its new state.

[164] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 48-53.
[165] Ibid.

Another methodology for determining reproduction cost is the *unit cost method*. This approach not only accounts for the development costs required to generate the intangible asset—i.e., direct costs—but also considers the totality of indirect costs necessary to bring the intangible to an operational state, along with the loss of productivity due to the time required to fully develop the intangible. This methodology is particularly useful for estimating the value of an assembled workforce, as the reproduction cost of an assembled and trained workforce, such as managerial roles, may require the appraisal of various direct and indirect costs, including:

i. *recruitment and hiring costs*, including salaries and benefits of employees involved in the recruitment and hiring process, head-hunter recruitment fees, overheads such as office space to conduct the recruitment process, other recruitment expenditures such as advertisements, pre-employment screening exams and relocation costs;
ii. *training costs,* including salaries and benefits of employees involved in the training process, overheads such as office spaces, other direct training costs such as training materials;
iii. *loss of productivity during the training phase,* as the new resource is compensated during the training period, during which it cannot contribute to the company's productivity due to a lack of the required skills[166].

In addition to these costs, Reilly & Schweihs recommend considering the developer's profit and the entrepreneurial incentive. The developer's profit represents a measure of cost, as it reflects a positive rate of return for the developer on their investment in the asset's development. This can be estimated by applying a markup to each unit of direct and indirect cost. Finally, the entrepreneurial incentive corresponds to the opportunity cost for the developer in engaging in the development process of the specific asset. The developer must be adequately incentivized to take on the risks associated with the development process by receiving a return sufficient to compensate for those risks[167]. Recalling the definitions provided earlier, the reproduction cost obtained does not, however, reflect the value of the intangible asset in question. In fact, this value, if considered on a stand-alone basis, reflects the cost of a new intangible asset. Therefore, it is necessary to adjust it for depreciation, which manifests as physical depreciation, functional obsolescence, and economic obsolescence, using the formula provided by Smith & Parr, with the exception that intangible assets are not affected by physical obsolescence as is the case with tangible assets, hence

[166] American Bankruptcy Institute, (2006), A guide to valuation of the assembled workforce intangible asset
[167] Reilly R., Schweihs R., (2014), Guide to Intangible Asset Valuation, 219-236.

removing the physical depreciation factor from the method.

The formula thus can be rewritten as:

$$FMV = CRN - FO - EO \quad [1.1.]$$

In which:

FMV = Fair Market Value
CRN = Cost of replacement new, alternatively expressed as cost of replacement
FO = Functional obsolescence
EO = Economic obsolescence[168]

It is worth noting that when valuing an intangible asset using the cost approach, certain limitations may arise, potentially leading to an inconsistent reflection of the asset's value. This methodology, although sometimes useful in the case of valuing software, assembled workforce, packaging designs, and distribution networks, has indeed some limitations. Firstly, the method does not calculate the amount of economic benefits derived from the ownership of the intangible asset, which, in turn, are based on its profit-generating capacity. Additionally, this method does not account for the duration over which such future economic benefits will be realized. To this end, the asset's conditions of use may be evaluated by applying a proportional coefficient between its remaining useful life and its total useful life, as illustrated in Equation 1.2.[169]:

$$V = C_t \times \frac{V_r}{V_t} \quad [1.2.]$$

In which:

C_t= Replacement cost
V_r= Residual useful life
V_t = Total useful life

The adjustments required by the method to account for the obsolescence of the intangible asset are determined independently and can sometimes be difficult to estimate. Lastly, the method does not take into consideration any risk factors on which to weigh the final value, and therefore, this aspect constitutes a disadvantage for adopting this valuation procedure in the case of intellectual property, making them more suitable for tangible asset valuation.[170]

[168] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 77-86.
[169] Guatri L. Bini M. (2005), Nuovo Trattato sulla Valutazione Aziendale, 179-200.
[170] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457.

3.3 The Market Approach

The market approach determines the value of the intangible asset by considering the price at which similar properties have been exchanged in arm's-length and open market transactions. Therefore, the market approach involves the analysis of comparable transactions, meaning transactions involving an intangible asset comparable to the asset being valued, from which the embedded price is extracted. This price becomes the key input for the valuation. The focus is thus on how the two parties involved in the transaction have priced the asset being compared.[171]: The price derived from the comparable transaction reflects the meeting of the wills of the buyer and the seller, thus providing a valuation of the intangible asset exchanged between independent parties. If there is sufficient comparability between the intangible asset being valued and the asset being exchanged, then there will be an indicator that reflects the risks and economic benefits derived from the ownership of the comparable asset, in other words an estimation of its fair value. As a result, this valuation method is a "practical means" of capturing the factors affecting the value of the assets, such as the expected future returns on the investment, the time frame of the returns, and the risks associated in generating these returns over that specific timing[172].

In order to determine a reliable value of the intangible asset through the application of the market approach, several conditions must be met. The first condition concerns the presence of an active market, that is, a liquid market where there is demand and supply for the asset in question.[173]The second condition refers to the presence of sufficient observable transactions, with known prices, that allow for the inference of the asset's value based on the prices of those transactions. Finally, these transactions must occur in an arm's length context, in order to eliminate any bias effects on the asset's valuation by the counterparties[174].

In the market approach, the difficulty lies in obtaining comparable transactions, which is why the market approach is often associated with the valuation of residential real estate: for such assets, it is relatively easier to identify comparison factors between previous transactions (sales and prices of already defined homes) and the potential sale being assessed. When it comes to a specific intangible asset, the likelihood of finding a sufficient number of transactions is limited, as is the probability of achieving a high degree of comparability between the two assets. The degree of comparability between intangible assets, and more specifically between intellectual property

[171] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 87-94.
[172] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457.
[173] Ibid.
[174] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 87-94.

assets, is subject to several factors. The industry in which the transaction is carried out is a fundamental comparability criterion, since comparable assets shall be exposed to similar economic cycles. Moreover the presence of similar profitability arising from the exploitation of that intangible is important: if the magnitude of the economic benefits attached to the assets are similar, then the two assets can be deemed to have similar economic relevance; an example of this can be extrapolated from the sports market, in which though several firms produce almost identical products, some brand names yield higher profit margins than others, due to the importance of the recognizable trademark among consumers[175]. Further comparability principles refer to comparable market share, new technology intertwined with the intellectual property right, similar growth prospects, similar remaining useful life, similar degree of barriers to entry, and similar legal protection. Particular attention must be paid to the last two criteria. Specifically, in the valuation of intellectual property rights, entry barriers—such as regulatory marketing approval for drugs in the life sciences sector—significantly increase the value of patents or trademarks associated with the drug. Consequently, the value of a patent supported by FDA or EMA approval is not comparable to that of a similar patent lacking such authorization, as the entry barriers are not equivalent. Similarly, as discussed in Chapter 2, much of the strategic value of intellectual property stems from exclusive legal rights[176]. To be more specific, in the case of patents, their value is largely derived from the legal monopoly they grant and the protection they offer against reverse engineering by competitors: The description and claims outlined in the patent provide legal protection for the invention. Therefore, in the Life Sciences sector, the more specific the claims, the stronger the legal entrenchment surrounding the patented drug, and consequently, the greater the value of the patent itself. As a result, two patents characterized by the same degree of specificity in their claims will enjoy stronger legal protection and, therefore, higher value. For this reason, their comparability will be greater.

Under the market approach the value of the intangible asset is thus derived by multiplying the market price multiple, obtained from comparable recent transactions, by an estimated sustainable driver of price[177]. Deriving the market price multiple is particularly challenging in the case of intellectual property rights. First, because there is no public trading platform for intellectual assets; second, due to the wide variety and variability of terms and conditions governing intellectual property exchanges; third, because of the inherently distinctive nature of such assets; and finally,

[175] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 87-94.
[176] Ibid.
[177] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457.

because of the strict confidentiality that typically surrounds these transactions, which are seldom disclosed to the public. In this context, it is important to consider that the majority of intellectual property rights (IPRs) transactions occur within broader deals, such as mergers and acquisitions (M&A), which involve a complex array of assets and resources. This necessitates intricate unbundling processes to isolate and determine the value of individual components. Consequently, for the application of this method in valuation, it becomes necessary to employ adjustment parameters on the prices embedded in these deals, thereby decreasing the degree of uncertainty in determining the asset's value.

Therefore, due to the difficulty in ensuring a sufficient degree of comparability between the asset object of valuation and the asset object of transaction, the scarcity of comparable transactions, and the lack of public information about them, the market approach is not highly suitable for valuing intellectual property rights. Nevertheless, its use can still be valuable in determining average values or variability ranges of certain information or parameters, which can serve as reference points for the valuation of intellectual property determined using other methodologies.

3.4 The Income Approach

The income approach values the intangible asset based on the present value of the economic benefit derived from its ownership, namely the future cash flows expected to be generated over the course of the asset's useful life, discounted at a rate of return capable of reflecting the time value of money and the inherent risk in achieving them.[178]

Among traditional valuation methods, the income approach is the only one that attempts to directly measure the fair value of a resource by discounting the future economic benefits that the intangible asset is expected to generate over its useful life, using *discounted cash flow* method as a guiding framework. For this reason, combined with the evident limitations imposed by of the application of the cost approach and the market approach, the income approach appears to be the most widespread method to value intangible assets.

The discounted cash flow method applied to an asset consists of calculating the net present value of the expected future free cash flows over the asset's life, discounted by a rate that captures the risk associated with the generation of future free cash flows. The discounted cash flow method, when applied to an asset with an indefinite useful life, can be encapsulated within formula 1.3. In this case, since the useful life of the asset is indefinite, the value of the asset will be equal to the sum of the discounted incremental free cash flows stemming from the ownership of the asset at every time period (t) within the explicit forecast period (N), and the terminal value, which reflects the residual cash flows beyond the explicit period, thereby capturing the going concern value of the asset. In addition, it must be specified that an intangible asset cannot have an infinite useful life, as maintaining an intangible asset indefinitely is only economically viable if the cost of maintaining the asset is lower than the future benefits derived from its use. This occurs when the economic depreciation of the asset, i.e., its loss of value due to obsolescence, exceeds the maintenance costs[179]. Clearly, in case of a definite useful life, the value of the asset, based on the discounted cash flow method, will be equal to the sum of the discounted future cash flows generated in each period of its remaining useful life, discounted for an adequate discount rate.

$$Value = \sum_{t=1}^{N} \frac{CF_t}{(1+r)^t} + TV \qquad [1.3.]$$

where:

N = Explicit forecast period.

[178] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457.
[179] Organismo Italiano di Valutazione, 2015, Italian Valuation Principles (PIV), 197-198.

CF_t = Incremental free cash flow generated by the asset in year t.

r = Discount rate applied, which accounts for the risk associated in achieving cash flows from the ownership of the asset and the time value of money.

TV= Terminal value, which in the general case of business valuation can be estimated either through the Exit Multiple Method[180] or the Gordon Formula[181].

In order to apply the income approach, it is necessary to quantify three key parameters:

i. The amount of future economic benefits derived from the exploitation of the intangible asset, i.e., the total net cash flows after taxes obtainable over the remaining useful life of the asset.
ii. The time period during which the income is expected to be received, estimated by assessing the magnitude of its remaining useful life.
iii. The discount rate for future economic benefits, i.e., a rate that reflects the risk associated with obtaining such future economic benefits, which corresponds to the return required by an investor for a particular asset class[182].

Turning attention to the first of the three parameters mentioned above, the estimation of the amount of future economic benefits can take the form of cash surpluses derived from reductions in operating costs, higher selling prices, or the sale of additional quantities, thereby fostering the earnings generated[183]. In this sense, the determination of the amount of forecasted net cash flows after taxes appears relatively straightforward when analysing an asset, whether tangible or intangible, that is already generating income. However, the calculation becomes significantly more complex if the asset or intellectual property under examination is not yet generating income, for instance in the case of patent under development[184]. In this regard, the estimation of future economic benefits must be carried out by considering the intrinsic characteristics of the asset to select the most appropriate methodology. Referring to the framework defined by the discounted cash flow method, the estimation of expected cash flows requires the specific identification of

[180] In the context of business valuation, the exit multiple method is based on the principle that a company at the end of the explicit forecast period can be sold for a multiple of a specific metric, such as EV/EBITDA or EV/Revenues. This exit multiple, when multiplied by the relevant economic metric, will give the company's enterprise value beyond the forecast period, thus determining the terminal value.

[181] The Gordon formula assumes that cash flows in the long term will grow at a constant rate, that is the long-term growth rate, thus reflecting a steady state of the operativity of the asset: $\frac{CF_N*(1+g)}{(r-g)}$

[182] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 87-94.

[183] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457.

[184] Hagelin T., (2002), A new Method to Value Intellectual Property. American Intellectual Property Law Association Quarterly Journal, Vol.30, 352.

those attributable solely to the intangible asset, and in this case, to the specific intellectual property under analysis. This activity often involves separating the expected economic benefits of the intellectual property from the overall amount of economic benefits derived from all the assets interacting with the intellectual property in the creation of value. There are various approaches for determining the flows of future economic benefits generated by the intangible asset, most of which start with the definition of free cash flow to the firm, or unlevered free cash flow. These free cash flows are calculated as unlevered, meaning they do not take the company's financial structure or financial interests into account, as these will be factored into the rate of return used to discount the free cash flow to the firm. The unlevered free cash flows are thus obtained starting from the revenues generated by the asset:

Revenue
− Cost of Goods Sold (COGS)
= Gross Margin
− General, Administrative, and Commercial Expenses (SG&A)
= Earnings Before Interest, Taxes, Depreciation, and Amortization (EBITDA)
− Depreciation and Amortization (D&A)
= Earnings Before Interest and Taxes (EBIT)
− Taxes[185]
= Net Operating Profit After Tax (NOPAT)
+ Depreciation and Amortization (D&A)
− Capital Expenditures (CAPEX)
− Changes in Net Working Capital (NWC)
= Unlevered Free Cash Flow (FCF)

In this formulation to derive the Unlevered Free Cash Flows, depreciation is first deducted from EBITDA to derive EBIT, on which taxes are applied to obtain NOPAT. Then, depreciation and amortization (D&A) is added back since it is a non-cash expense. The result of this process implies the presence of tax amortization benefits arising from the exploitation of the intangible asset. Since amortization can be deducted for tax purposes, the company can reduce the taxable income represented by the operating profit (EBIT). Consequently, lower taxes imply an increase in the unlevered free cash flow, ceteris paribus. Moreover, as D&A is added back when calculating the

[185] Taxes are calculated by applying the effective tax rate to the EBIT, for Italian Entities being equal to the sum of the tax rates related to Corporate Income Tax (IRES) and Regional Tax on Productive Activities (IRAP).

unlevered free cash flow (being a non-cash item), its impact produces a tax shield for the company. This tax shield is identified as the reduction in taxes equal to the effective tax rate multiplied by the annual amount of amortization traceable to the Intangible Asset. Consequently, it is possible to detect the first economic benefit arising from the ownership of the intangible assets: being subject to amortization over their remaining useful life, intangibles and thus intellectual property assets yields tax amortization benefits (TAB).

The future economic benefits derived from the ownership and exploitation of the intangible asset can be captured in multiple ways under the income approach. In valuation practice, the variants of the income approach to be referred to in identifying future economic benefits must be anchored to the type of intangible asset being evaluated and the availability of sufficient information to apply a particular methodology. Over time, academic literature has revealed the presence of several subtypes of the income approach for valuing intangible assets that, according to Smith & Parr, can generally be divided into two broad categories: *direct methodologies* and *indirect methodologies*. Direct methodologies estimate the future economic benefits generated by the intangible asset by isolating the specific economic benefits related to the asset in question. Naturally, this methodology depends on the availability of sufficient information regarding the specific economic benefits generated by the intangible. Indirect methods, on the other hand, analyse general market information or broader business performance metrics and then attribute a portion of those economic benefits to the asset in question. On the other hand, Reilly & Schweihs They provide a more granular categorization of the methodologies stemming from the income approach, such as:

i. *Income methods that rely on a differential income,* based on the principle according to which the owner of the intangible will generate a higher amount of revenue or lower amount of operating costs by owning the intangible asset compared to not owning the intangible asset, as in the case of the *With and Without Method*. The differential income may be also compared to industry benchmark income measure, as in the case of *profit margin differential*;
ii. *Income methods that estimate a relief from royalty payment related to a hypothetical license agreement,* which estimates the future economic benefit arising from the ownership of the intangible asset in terms of relief from royalty payment to exploit the asset;
iii. *Income methods that rely on hypothetical agreements between the owner of the intangible and the operator,* based on the principle according to which the two *will*

share the expected profits from the commercial exploitation of the intangible asset;

iv. *Residual income methods that typically start with the owner's total business income,* based on the residual income arising from the differential between total business income and contributory asset charges (CACs), as in the case of the MPEEM[186].

The discussion of traditional income approach methodologies will be addressed in the following sections. Additionally, it is presented a range of supplementary approaches that fall outside the boundaries of strict categorization, which are thus identified as alternative methodologies. Before decomposing each valuation methodology, it is also necessary to clarify the determination of the other two key parameters for the applicability of the income approach: the estimation of the remaining useful life of the intangible asset and the determination of the appropriate discount rate to apply to the future economic benefit stream.

3.4.1 Remaining Useful Life and Tax Amortization Benefits

The remaining useful life of the intangible asset under valuation is a crucial parameter in order to determine its fair value measurement under the income approach. The remaining useful life hereby RUL, is fundamental in order to determine the time frame over which amortization is determined and the time horizon covered by the projections of future economic benefits arising from the ownership of the intangible asset. Indeed, the RUL directly impacts the value of the intangible, as the longer is the RUL, the higher is the magnitude of future economic benefits and the tax amortization benefits. It is important to remind that the RUL is also crucial for the application of the cost approach, as it allows the estimation of the obsolescence of the asset.

The Financial Accounting Standard Bord, outlines asset several factors that should be accounted when determining the useful life of the intangible asset:

v. Expected use of the asset by the entity;
vi. Expected useful life of another asset or group of assets to which the useful life of the intangible may relate;
vii. Legal, regulatory, contractual provisions that may limit the useful life;

[186] Reilly R., Schweihs R., (2014), Guide to Intangible Asset Valuation, 219-236.

viii. Entity's own historical experience in renewing or extending similar arrangements regardless of explicit renewal provisions;
ix. Effects of obsolescence, demand, competition, and other economic factors;
x. Level of future maintenance expenditures required to obtained the future economic benefits from the asset[187].

Some intangible assets are entrusted with indefinite useful life, which means that the asset does not have any legal nor economic limitation in its potential usefulness: in other words, the asset's useful life is uncertain. An example of intellectual property asset with indefinite useful life are trade names. As mentioned in the previous section, it is important to clarify that indefinite useful life does not overlap with the concept of infinite useful life, since infinite useful life implies no end to the functional period of the asset[188]. As a result, the asset in this case can't be amortized, however is subject to annual impairment tests.

The useful life of certain intangible assets is defined within the boundaries of legal and contractual relationship, the term of a specific legal right or a contractual relationship that establishes the asset's existence determines the length of its useful life. In these cases, the useful life overlaps with the legal or contractual life of the assets. Intellectual Property assets stems from legal rights; therefore, their legal life is defined by the regional regulatory framework that the firm must adhere to. Stripping away regional differences in IP regulations, patents in general have a legal life comprised between 14 to 20 years, copyrights originated after 1978 lasts throughout the author's life plus 70 years after the author's death, and trademarks do not have any legal limitation in their duration[189]. In parallel, some intangible assets may be conveyed by agreements whose clauses determine the duration of the ownership of that specific intangible asset as in the case of license agreements and franchise agreements.

The useful life of an intangible asset is also affected by its economic life, i.e. the period of time during which the asset is profitable and thus contributes to the cash flow generating ability of the firm[190]. The economic life of an asset thus terminates when the intangible is no longer profitable, hence the cash flows generated thereafter are immaterial due to changes in

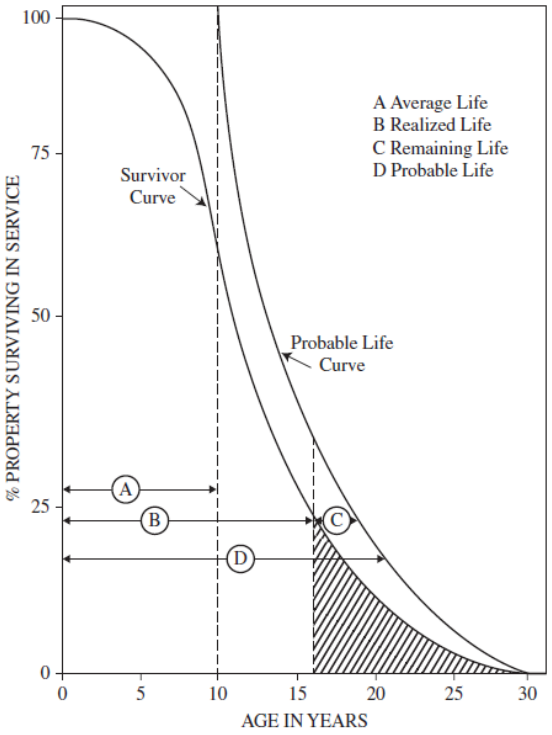
[187] Vulpiani M., (2014), Special Cases of Business Valuation, 453-457; Zyla M, (2020), Fair Value Measurement, 283-296.
[188] FASB Accounting Standards Codification (ASC) 350.
[189] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 507-520.
[190] Zyla M, (2020), Fair Value Measurement, 283-296.

external economic conditions. Under the income approach perspective, the economic life is the period that impacts directly the valuation of the intangible asset, as it creates the boundaries within which economic benefits materialize. Economic life sometimes takes higher priority than an asset's legal life: a patent that still has 5 years until its expiration may have null value if the patented invention becomes suddenly obsolete due to changes in economic and technological conditions. Therefore, estimating the economic life of the intellectual property asset proves to be crucial for the determination of its fair value under the income approach.

The academic literature outlines various methods to estimate the economic life of the intangible asset, which are deeply interconnected with statistical analysis based on historical data of a specific metric that mirrors the economic benefits of the asset under valuation. One statistical method employed for the estimation of the future pattern of the economic life of an asset is the *survivor curve*. Survivor curve estimates the amount of retirement data connected to the asset in order to estimate the surviving data over time[191]. Exhibit 3.3 illustrates an example of survivor curve, in which the Y-axis reports the percentage of property surviving throughout the stages of the economic lifecycle of the asset, in units of time (years), which is reported on the X-axis. Generally, the survivor curve is a reverse S-shape curve which renders the trend the pace at which property units retire every year: the area under the curve represents the service yielded by the asset during its economic life, which reduces at faster pace, the curve become steeper, as time increases, however, to become flatter towards the final year of the asset. From the trend shown in the survivor curve it is possible to infer a probable life curve, whose horizontal distance from the survivor curve at any given point of time will determine the remaining life. Moreover, it is important to clarify that time itself is not the cause of the decay of the retirement of property data, rather it is the unit of measure to capture the survivorship of future economic benefits yielded by the asset.

[191] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 507-520.

Exhibit 3.3 *– Example of Survivor Curve.*



Source: Smith & Parr, 2005.

Some intangible assets are based on customer relationships, rather than contractual relationship, thus the estimation of the residual useful life takes the form of statistical analysis of the attrition of customers over time: in other words, estimating the percentage of customers surviving every year of the life cycle, and thus basis of estimation of revenues generated by the asset over time, until the surviving customers are null. In order to assess the pace at which customers retire every year, thus the slope of the survivor curve, an attrition rate must me determined. The attrition rate or churn rate is mainly based on two factors, which are traceable to the level of growth that comes from existing customers, and the level of revenues dissipated due to customer attrition[192]. Customer attrition can be estimated by taking into consideration the historical trend of either customer turnover generated solely by the intangible asset (disaggregate approach), or customer turnover imputable to the intangible asset stemming from the total customer turnover (aggregate approach)[193]. The aim in this case is to understand the magnitude of customer turnover that has been lost historically every year, determining the future rate of decay of customer revenues (Attrition Rate), and hence the retention rate as it can be defined as 1-Attrition Rate (%), estimating the future revenues survivorship curve.

[192] Zyla M, (2020), Fair Value Measurement, 283-296.
[193] Ibid.

Therefore, the methods for the estimation of the survivor curve of customer relationship-based intangible assets the attrition rate represents a key input. The valuation practice has identified several methods for the estimation of the survivor curve, depending on how the attrition rate is treated, examples of these methods are:

i. *Constant Number Method;*

ii. *Constant Attrition Rate Method;*

iii. *Variable Attrition Rate Method*[194].

The Constant Number Method estimates the survivor curve based on the application of a flat rate of decay, thereby developing a downward sloping curve characterized by a constant slope, as for every year of the RUL, the magnitude of the customer retired remains constant. On the other hand, the Constant Attrition Rate Method is based on the application of a stable rate for each year of the RUL, thereby being factored inside an exponential function.[195]. In addition, the exponential function takes into consideration the customer relationship age, thus combining it with the churn rate, in order to return a customer's average useful life equal to the customer's average residual useful life[196]. The constant attrition rate method thus determines the survivor curve as described in equation 1.4:

$$S_t = e^{\left(\frac{-t}{v}\right)} \qquad [1.4]$$

In which:
S_t = survival rate at a determinate customer relationship age (t)
t = customer relationship age
v = exponential curve factor deriving from -1/ln(1-AR)
AR = attrition rate, thus 1-AR is the portion of customer retained.

Finally, the Variable Attrition Rate method estimates the survivor curve by applying a variable decay for each year of the intangible asset's remaining useful life, by taking into consideration directly the age of the customer relationship: thus, the method is based on the calculation of a new attrition rate for each year derived from the analysis of historical data, thereby developing

[194] Guatri L. Bini M. (2005), Nuovo Trattato sulla Valuatazione Aziendale, 179-200.
[195] Vulpiani M., (2014), Special Cases of Business Valuation, 465-470.
[196] Ibid.

a stochastic model to estimate the probability and the intensity of the attrition in each year[197]. The results of the application of survivor methods are the determination of the remaining useful and the economic life of the intangible asset within which the asset is expected to generate future economic benefits. The remaining useful life is a key parameter for the estimation of the tax amortization benefits. Since intangible assets with definite useful life can be amortized, the amortization costs produce a reduction in the taxable income, hence creating an economic benefit arising from the ownership of the intangible asset. For this reason, when valuing intangible asset, it is important to also capture the amount of future tax amortization benefits. Consequently, the value of the intangible asset derived from applying the income approach methodology is added to the amount of tax amortization benefits to provide a comprehensive consideration of all future economic benefits. It should also be emphasized that TABs can be added to the value identified through the cost approach, however, they cannot be added to the value determined using the market approach, as it already includes the tax amortization benefits[198].

Tax amortization benefits are a function of the fair market value of the intangible asset, since the present value of cash flows from the intangible asset represent the base on which tax savings over the remaining useful life are computed. Therefore, in order to calculate the TAB formula 1.5 can be applied:

$$TAB = PVCF \times \left(\left(\frac{RUL}{RUL-\left((PV[r;RUL;-1]\times(1+r)^{0.5})\times t\right)}\right)-1\right)$$

[1.5]

Where:

TAB = Tax amortization benefits

$PVCF$= present value of cash flows from the intangible asset

RUL = remaining useful life

r = discount rate

t = tax rate

But since to calculate the tax amortization benefits it is required to have the fair market value of the intangible asset, a problem of circularity arises since TAB also is needed to determine

[197] Figini S, (2006), Customer Relationship: a survival analysis approach.

[198] Organismo Italiano di Valutazione, (2015), Italian Valuation Principles (PIV), 200-201.

the value of the asset[199]. The circularity issue can be solved by taking into consideration the fair market value of the intangible asset equal to the product between the fair market value without considering TAB and a *TAB factor,* replicating the rational to which the fair value of the intangible asset is the base for the calculation of tax amortization benefits.
Thus, fair market value of the intangible asset can be calculated as in formula 1.6:

$$FV_{intangible\ Asset} = FV_{before\ TAB} \times TAB_{factor} \quad [1.6]$$

Where the TAB factor is calculated as follows:

$$TAB = \frac{RUL}{RUL - \left((PV[r; RUL; -1] * (1+r)^{0.5}) * t\right)}$$

3.4.2 Cost of Capital and Intangible Assets

Before delving into the intricacies of estimating the appropriate cost of capital to value an intangible asset, it is necessary to revisit the assets that define the business enterprise value and their impact on risk.
The asset side of a business can primarily be characterized by four types of assets that contribute to income generation and, ultimately, to the risk profile of the business. These assets can be classified as *monetary assets, tangible assets, intangible assets, and intellectual property assets*[200]. Monetary assets are primarily composed of the differential between current assets (such as receivables, inventories, and other current assets) and current liabilities, including accounts payable, accrued salaries, and accrued expenses. If one considers, for example, the speed at which receivables are collected, it can be stated that monetary assets are the most liquid; therefore, they associated with low inherent risks, that can be comparable to the risk of investments in money market funds.[201]
Tangible assets, such as plants, equipment, and office buildings, on the other hand, have a lower degree of cash conversion, yet they are characterized by an extent of marketability. This marketability, however, can be severely impacted by market conditions, as in the case of real estate

[199] Vulpiani M., (2014), Special Cases of Business Valuation, 462-463; Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 161.
[200] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 108-112.
[201] Ibid.

crises. As a result, the inherent tangible assets are riskier than monetary assets.

Intangible assets and intellectual property represent the riskiest class of assets within a company's balance sheet. These assets characterized by low degree of liquidity, but most importantly they are characterized by the risk of obsolescence. Obsolescence can immediately eliminate the associated future economic benefits without the possibility of redeployment of the asset, unlike tangible assets.

Therefore, the appropriate cost of capital should effectively reflect the inherent risk associated with the intangible asset under valuation.

When valuing business enterprise value, the cost of capital applied to carry out the income approach is the weighted average cost of capital (WACC). The WACC accounts for the rate of return that an average investor, shareholder and bondholder, require to provide capital to the firm. Thus, the WACC takes into consideration both the required rate of return for providing equity capital (cost of equity), and the required rate of return for providing debt capital (cost of debt after-tax), weighted for the firm's capital structure, as understandable from formula 1.7:

$$WACC = K_e \times W_e + K_d \times W_d \times (1 - t) \qquad [1.7]$$

In which:

K_e = Cost of Equity

W_e = Weight of Equity on total Capital

K_d= Cost of Debt

W_d= Weight of Debt on total Capital

t = Tax rate[202]

The literature concerning the estimation of the appropriate cost of capital for valuing intangible assets appears to be quite fragmented, as there is not a unique generally accepted estimation method. According to a stream of academic literature, the rate of return used to value an intangible asset depends on the purpose of its valuation, which may take the form of assessing the intangible asset as an integral part of the business operations of an entity or as a stand-alone asset[203]. According to Reilly F. and Schweihs R., the weighted average cost of capital (WACC) can be

[202] Since interest expenses are tax deductible, debt financing reduces the taxable income thereby creating interest tax shields. As a result, the cost of debt will be reduced by an amount equal to the tax benefits arising from interest expenses, hence it is required to calculate the cost of debt after taxes.

[203] Reilly R., Schweihs R., (2014), Guide to Intangible Asset Valuation, 219-236.

considered as a proxy for determining the discount rate for valuing an intangible asset when it contributes to the going concern of a business. If the intangible asset contributes to the income generation of the overall business, its rate of return is subject to the same risk profile as the entire business. Therefore, the rate of return for the intangible asset will be a function of the rate of return for the entire business, aligning with the WACC. However, in cases where the valuation of the asset is conducted as a stand-alone element, thus not contributing to the going concern, its rate of return cannot overlap with the WACC, as this would underestimate the inherent risk of the intangible asset. As mentioned previously intangible assets fall within the riskiest asset class, thereby having significantly higher risks than the business as a whole. On top of that, WACC takes into consideration interest tax shields, thereby capturing a reduced quantity of business risk, hence if WACC were to take as discount rate, this would result in underestimation of intangible asset inherent risk.

Taking into consideration the view of Smith and Parr, business enterprise value is constituted by the sum of fair market value of monetary assets, tangible assets, and intangible assets, as referenced in formula 1.8:

$$EV = M_A + T_A + I_A \quad [1.8]$$

In which:

EV = Business Enterprise Value

M_A= Monetary Assets Fair Value

T_A = Tangible Assets Fair Value

I_A = Intangible Asset Fair Value

Based on this formulation, the rate of return of the business as a whole, must be a function of the contribution of each asset, which ultimately participate to the generation of future economic benefits and to the determination of the business overall risk. Consequently, the WACC will be determined by the aggregate of all the rates of return of the assets that constitute the enterprise value. This forms the foundational assumption of the WARA (Weighted Average Return on Assets) method, which posits that the sum of the rates of return of each asset, weighted by the proportion of its fair market value relative to the enterprise value, aligns with the WACC.

In this context, a reliable rate of return for intangible assets can be obtained residually, by estimating a rate of return (r_i) such that Weighted Average Return on Assets can reconcile with

WACC after tax, as shown in formula 1.9:

$$WACC = \frac{V_m}{EV} \times r_m + \frac{V_t}{EV} \times r_t + \frac{V_i}{EV} \times r_i \quad [1.9]$$

In which:

V_m= Monetary Assets Fair Value

V_t = Tangible Assets Fair Value

V_i = Intangible Asset Fair Value

r_m= Rate of return of Monetary Assets

r_t = Rate of return of Tangible Assets

r_i = Rate of return of Intangible Assets

EV= Business Enterprise Value

Based on the application of the WARA method, Smith & Parr identify the unlevered cost of equity as the most reliable proxy for capturing the rate of return of intangible assets. They further assert that this choice is consistent with the fact that intangible assets are usually equity-financed, thus justifying the exclusion of leverage effects. On the other hand, Stegink, Schauten, and Graaff modify the paradigm of the WARA method employed by Smith e Parr, considering the present value of tax shields as a separate item in the computation of WARA, as shown in formula 1.10:

$$WACC = R_e \frac{E}{E+D} + R_d \frac{D}{E+D} = WARA = R_{MA} \frac{MA}{V_L} + R_{TFA} \frac{TFA}{V_L} + R_{IA} \frac{IA}{V_L} + R_{PVTS} \frac{PVTS}{V_L} \quad [1.10]$$

Where:

WACC = Weighted Average Cost of Capital of the company before tax

R_e= Levered cost of equity

R_d= Cost of Debt

R_{MA}= Required return on monetary assets

R_{TFA}= Required return on tangible fixed assets

R_{IA}= Required return on intangible assets

R_{PVTS}= Required return on tax shield

Under this new formulation, the return on intangible assets (R_{IA}) can be estimated residually, this time accounting for the rates of return on tax shields, as they are treated as separate items with a required rate of return. Present value of interest tax shields is accounted as a separate item since the inclusion in the cost of debt after tax would imply a lower cost of capital, and thus an underestimation of the required rate of return on intangible assets. Using this WARA formulation, the authors calculate the rates of return on intangible assets across eight different sectors of the S&P 500. Once derived the cross-industry rates of return on intangible asset, are compared to three potential proxies, identified previously by the literature as sufficient surrogated rate of return on intangible assets: the WACC, unlevered cost of equity, and cost of equity. The conclusions of the analysis revealed that the levered cost of equity can be considered as the most accurate estimator, among the three proxies.
The reconciliation of WACC-WARA is a method that proves to be useful in cases of purchase price allocation, and specifically when applying income methods such as the Multi Period Excess Earning Method, discussed in the following section: thus, in this case a plausible rate of return for the intangible asset will be derived as the missing piece that is needed to reconcile the WARA and the WACC of the company.

Empirical evidence has also revealed the existence of specific benchmark rates for each class of intangible asset. In such cases, it is not uncommon to use these benchmark rates as a starting point, or "plug-in," which can then be adjusted for specific risks inherent to the asset under evaluation. In such cases, a rule-of-thumb approach can be applied, referencing rates identified through empirical research for a specific family of intangible assets. This involves applying the rate corresponding to the family to which the asset under valuation belongs. Examples of this approach are illustrated in case studies, such as those highlighted by Mard, Hitchner, and Hayden, who adopted the following discount rates for specific intangible asset classes, obtained through the prism of the market participants[204], as depicted in Exhibit 3.1:

[204] Mard M., Hitchner J., Hayden S., (2012), Fair Value, Business Combinations, Intangible Assets, Goodwill, and Impairment Analysis 71-129.

Exhibit 3.1 *- Rate of Return for each Asset Class assumed by Mard, Hitchner and Hyaden*

Rate of Return for each Asset Class assumed by Mard, Hitchner and Hayden	
Software	17.00%
Assembled Workforce	16.00%
Tradename	16.00%
Noncompete Agreement	16.00%
Technology	18.00%
In-process R&D	20.00%
Customer Base	17.00%

Source: Mard M., Hitchner J., Hayden S., (2012),

As can be observed, the authors adopted these rates of return, attempting to capture the higher risks inherent in certain asset classes, such as In-Process R&D, by applying a higher discount rate. While the use of benchmark rates for specific asset classes offers a quick approach, this approach is significantly flawed; it would be unrealistic to assume that two intangible assets belonging to the same asset class but owned by two companies of different sizes and business risks would be characterized by the same rate of return[205]. In addition, considering these empirical rates of return as a stand-alone plug-in value would imply potential inconsistency issues with respect to the cost of capital of the whole firm. The basic principle here is that the entirety of the rate of returns of the assets constituting the business enterprise value should reconcile in the end with the WACC: hence, applying standardized rates of return without considering the peculiarity and the risks of the business will generate a discrepancy between WACC and the weighted average returns of all the constituent assets. For this reason, in order to maintain a consistency principle, the returns on each constituent asset should be anchored in a direct relationship with the WACC, as outlined in the following formula:

$$WACC = \sum_i^N C_i \times W_i \qquad [1.11]$$

[205] Vulpiani M., (2014), Special Cases of Business Valuation, 460.

Where:

C_i= cost of capital of asset i

W_i= value weight of asset i

In other words, this formulation can be conceived as an extension of the WARA method to the totality of business assets weighted for their fair value contribution to the enterprise value. Hence, the cost of capital of a specific intangible asset (C_n) will be derived in a residual way as a function of the WACC and the other asset's rates of returns[206]:

$$C_n = \frac{WACC - \sum_i^N C_i \times W_i}{W_n} \quad [1.12]$$

Finally, another possible approach to estimate the cost of capital of a single intangible asset can stem from the application of a specific risk spread to the WACC. The risk spread arises when comparing the return of a specific intangible asset to the average return of the identifiable intangible assets. In case of an asset whose risk can mirror the overall business risk the WACC can be used as a discount rate; however, in presence of riskier assets such as In-Process R&D, as outlined by the case study of Mard et. Al, a spread shall be applied to the WACC in order to avoid underestimation of its risk.

3.4.3 Traditional Income Approach Methods

The valuation practice has introduced over time multiple income methods, often characterized by slight modifications to previously developed methods. Referring to the categorization provided by Reilly F. and Schweihs R., the traditional methodologies explored in this section are:

i. *Incremental Income Methods*, such as *the With and Without Method* and *Profit Margin Differential* method;
ii. the *Relief from Royalty Method;*
iii. the *Profit Split Method – 25% Rule;*

[206] Ibid.

iv. *Multi-Period Excess Earnings Method*.

Incremental Income Methods

The with and without method (WWM) stems from the family of income methods that rely on a differential income. This method is based on the principle according to which the value of the intangible asset can be derived from a comparison between two equal firms, which differ in terms of ownership of that specific intangible asset: thus, the value of the intangible asset, such as a trademark or a brand name, is inferred by quantifying the incremental cash flows arising from its ownership versus the absence of its ownership. Sources of incremental cash flows can be traceable to incremental revenues or incremental cost savings from owning the intangible asset versus not owning it[207].

Incremental revenues can arise from price premiums or additional volumes generated by the exploitation of the intangible asset. In case of intellectual property, firms that own trademarks can charge mark-up prices with respect to generic products: this is justified by the fact that customers associate higher value and quality to the trademark name rather than a generic product. Moreover, trade secrets and patents can exert premium prices, stemming from the presence of a unique secret technology against competitors for trade names, and from a legal monopoly right in the case of patents. In case of pharmaceutical companies, the premium prices can be tangibly detected by comparing patented drugs versus generic drugs: in this case, the premium price leads to higher profitability since manufacturing costs are similar between the owner of the patent and the generic manufacturer, however this does not hold true in case of R&D investments as the patent owner invested significantly more in R&D to come up with the final molecule.

On the other intangible assets, and as such intellectual property assets, can increase operating cost savings for the owner, without sacrificing the quality of the manufactured product. Examples of cost savings arising from intangible asset exploitation can be: increases in the amount of production output per unit of labour input, reduced use of utility in the manufacturing process, improved quality thereby reducing product recall[208].

The method bases its application on the development of two separate scenarios: one considering the status quo of the business, thus with the intangible asset in place, and a scenario reflecting the business without the intangible asset. To develop the two scenarios, it is required to estimate the

[207] Hyan M., Schlegel O., (2021), Incremental Cash Flow Method.
[208] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 98-102.

RUL of the intangible asset, and make assumptions on the revenues and cost advantages deriving from its exploitation, in order to identify the EBITDA, NWC, D&A and Capex for each year of the RUL. The projections of the free cash flow to the firm arising from the two scenarios are then compared, thereby identifying the incremental free cash flows for each year of the RUL. Each delta free cash flows are then discounted with an appropriate cost of capital, capable of reflecting the inherent risk of the intangible asset, which according to Smith & Parr can be assumed equal to the WACC. Finally, as can be seen from formula 1.13, the sum of the discounted delta cash flows is added to the tax amortization benefit (TAB) based on the RUL of the intangible asset[209].

$$V_i = \sum_{n=1}^{T} \left(\frac{CF_n\ incl. - CF_n\ excl.}{(1+r)^n} \right) + TAB \qquad [1.13]$$

In which:

n = Period

T = Total number of periods identified within the RUL

$CF_n\ incl.$ = Cash flow of period n including the intangible asset

$CF_n\ excl.$ = Cash flow of period n excluding the intangible asset

r = Cost of capital of the intangible asset

TAB = Tax amortization benefit

The With and Without Method is based on the principle according to which the intangible asset, such as the intellectual property, is responsible of the additional cash flow compared to a scenario that entails its absence. However, these additional cash flows can be yielded only if the intangible asset is combined with other assets: hence, the method turns out to be not ideal to value an intangible asset on a stand-alone basis. Moreover, the applicability of the WWM is subject to the availability of data inputs to determine the "without" scenario[210]: since it is difficult to determine situations in which comparable business operations can be identified without a specific asset, the method may be impacted by flawed assumptions used for the development of the "without" scenario.

Smith & Parr suggest a further approach stemming from the family of incremental income methods: the *profit margin differential approach*. The profit margin differential approach bases its

[209] Hyan M., Schlegel O., (2021), Incremental Cash Flow Method.
[210] Ibid.

valuation principle on the comparison of a normal industry profit margin and an enhanced profit margin attributed to the intellectual property asset. In this case, the differential between the profit margin incorporating the intellectual property and a normal industry profit margin can capture the added value of the intellectual property asset in business operations. This approach has been historically used to identify the royalty rate to quantify IP infringement damages, as can be seen in the following equation:

$$Expected\ Profit\ Margin - Normal\ Profit\ Margin = Royalty\ Rate \quad [1.14]$$

Therefore, according to this equation, the infringer shall correspond a royalty rate to the owner if the profit margin earned is higher with respect to the profit margin benchmark of the industry. The bottom line of this approach is thus quantifying the "normal" profit margin of the industry, which is not an easy task to accomplish: indeed, companies in the same industry may have widely different profit margins because of market competition, internal differences due to various service lines within business operations, and stages of the product lifecycle. Moreover, another important difference lies on the contribution of other assets, such as tangible assets, to the profit margin of the company. This particularly holds true for capital intensive industries, in which the excess profit margin can be a result of the combination of the intellectual property and fixed assets investment to allow the exploitation of the very same intellectual property asset. Therefore, in light of these factors it results quite challenging capturing the exact contribution of intellectual property to the overall profit margin for several industries. For this reason, Smith & Parr suggest that the profit margin differential method might be suitable when considering sectors that market commodity products to determine the profit margin benchmark: commodity products are standardized, lacking brand names, and they are characterized by thin profit margins due to high competition. Hence for these industries it is possible to identify a normal profit margin, thereby capturing the added value of intellectual property as in the case of trademarks[211].

Relief from royalty method

The relief from royalty method captures the value of the intangible asset, by estimating the cost savings represented by the royalty payments the company would have incurred to use the intellectual property if it did not own it. As seen in chapter 2 the object of licensing agreements is

[211] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 103-107.

often based on intellectual property rights, for this reason the relief from royalty method can be considered more suitable when valuing intellectual property assets. The relief from royalty method takes the intellectual property asset under a transactional perspective. If a firm does not own a trademark nor a patent it is required to enter in an arm's length licensing agreement with the owner, in order to grant its exploitation right. Hence, since the firm owns the intellectual property under consideration, the firm can be deemed "relieved" from corresponding the royalty payments arising from the theoretical licensing agreement. Under this method the future economic benefits of the intellectual property materialize in the present value of royalty savings after tax along its remaining useful life. In order to estimate the royalty savings, the first step is to determine the base on which royalty payments are computed within the theoretical licensing contract. In a licensing agreement the licensor may grants the right of the intellectual property to the licensee in exchange for royalty payments. These royalty payments are derived from the application of a royalty rate on different performance metrics such as:

i. Total Sales;
ii. Net Sales;
iii. Profits;
iv. Monetary Value per unit sold;
v. Monetary value per unit produced.[212]

Sales are the most common royalty base in a licensing agreement, as they are preferred over profits due to lower risks for the licensor in obtaining royalty payments, since the licensee may not be able to exploit the full potential of the licensed intellectual property thereby capitalizing losses over time. Moreover, sales revenue is commonly used as a starting point for the relief from royalty method, since the metric is not affected by company specific differences, such as financing and operating expenses[213].

For the sake of the application of the relief from royalty method the royalty base, such as sales revenue, is required to be computed having consideration of the portion generated by the single intellectual property asset. Therefore, financial projections of the net sales stemming from the intellectual property are developed, bearing in mind specific risk adjustments and additional expenses to effectively enforce the intellectual property right over its remaining useful life. As a

[212] Hubscher M, Erhart S., (2021), Intangibles in the World of Trasnfer Pricing, 283-298.
[213] Vulpiani M., (2014), Special Cases of Business Valuation, 464.

result, some practitioners may add an expense line to the royalty base to reflect the expenses that can be occurred when securing the rights from intellectual property, such as administrative costs that are required to protect the intellectual property from infringement and marketing costs required to promote the brand name[214].

Once identified the royalty base, in order to derive the stream of royalty payments, a royalty rate must be identified. The identification of the appropriate royalty rate is generally based on comparable royalty rates observable in arm's length licensing agreements, that can be assumed typical for the industry in which the intellectual property is exploited. The degree of comparability among royalty rates is based on how similar the asset under license is, and how similar is the industry sector in which the licensing agreement takes place. Moreover, the degree of comparability is extended to various economic parameters that characterize the licensing contract. Geographical terms of use are analysed in order to understand the comparability in terms of geography, giving priority to licensing agreements occurring in the same country where the owner of the intellectual property right under valuation operates. Moreover, temporal terms of use are taking into consideration to understand to which extent the remaining useful life of the asset is comparable to the expiration of the licensing agreement. Permitted forms of use, such as sales license or manufacturing license should be consistent with the type of intellectual property under valuation. Finally, the degree of exclusivity and the type of financial obligations are screened to assess the comparability of the royalty rate[215].
The royalty rates observable in market licensing agreements should be adjusted in order to fully reflect the peculiarities and the risks characterizing the intellectual property asset. Often, market royalty rates are affected by distortive factors such as the financial structure of the deal, which may imply the presence of upfront payments. Moreover, several licensing agreements are influenced by legal proceedings thus making negligible the concept of arm's length transaction. Finally, for certain industries public data concerning the licensing agreements may not be available, forcing to shift the analysis on other industries to find surrogate measure of comparable royalty rates. For this reason, conversions from market data to the appropriate royalty rate are required, however bringing a higher degree of subjectivity in the making.

By applying the appropriate royalty rate to the royalty base, it is possible to derive the royalty

[214] Hubscher M, Erhart S. (2021), Intangibles in the World of Trasnfer Pricing, 283-298.
[215] Ibid.

payments for each period of the remaining useful life, and hence the cost savings associated with the ownership of the intellectual property. Tax savings realized by the licensee are then deducted from the cost savings, since royalty payments are tax deductible, and the owner cannot benefit from the royalty tax shield: the local tax rate is thus applied to the pre-tax royalty savings. Subsequently, the stream of after-tax royalty savings of the intellectual property asset is discounted using an appropriate cost of capital for each period of its remaining useful life. Finally, to determine the value of the intellectual property asset, the present value of after-tax royalty savings is combined with the TAB to incorporate the tax amortization benefits derived from owning the intangible asset[216].

To apply the methodology effectively, it is important to clarify that if the royalty rate is derived from licensing agreements transferring only a portion of the rights to the licensee, the resulting relief from royalty payments cannot fully capture the complete economic benefits: the sole cost savings from royalty payments related to a portion of the intellectual property rights could underestimate the real value of the intellectual property[217]. In this case the relief from royalty is only able to capture a fragment of the total value of the intellectual property asset, as it is capable to appraise only the value of the licensee's intellectual property rights; however, the value of the licensor's intellectual property rights is still yet to be appraised. From this perspective the fair value of the intellectual property (V_i) will be equal to the sum of the value of licensor's rights (V_o) and licensee's rights (V_l)[218].

$$V_i = V_o + V_l \qquad [1.15]$$

Profit Split Method – The 25% Rule

An income approach based on a logic similar to the relief from royalty method is the profit split method. This method is founded on the principle according to which the value of an intangible asset can be derived by considering the terms of a licensing contract. Under licensing agreements, it is common to divide the total profits generated by the licensed intellectual property between the licensor and the licensee. Consequently, from the licensor's perspective, the value of the

[216] Vulpiani M., (2014), Special Cases of Business Valuation, 464.
[217] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 101-104.
[218] Ibid.

intellectual property asset can be reflected in the present value of royalty payments over its useful life, calculated based on incremental profits using a royalty rate corresponding to the profit split ratio[219]: the result will be equal to a current year lump-sum deriving from a hypothetical licensing agreement. Therefore, the profit split method tries to allocate the value of the intellectual property between licensor and licensee, on the basis of a profit split ratio.

The royalty rate can be derived by exploiting the rule of thumb according to which in a standard licensing agreement, the licensor will receive 25% of the profits generated by the licensee[220]. The rule of thumb is based on historical evidence that shows a 25/75 split in licensing agreements, in which the licensee will retain 75% of the profit generated to be compensated for the risks taken to develop and commercialize the underline product[221]. Moreover, Razgaitis provides further justifications of the 25% rule, asserting that the rule of thumb holds true since:

i. 75% of the investments for the development and the commercialization of the product are undertaken by the licensee;
ii. licensees have stronger contractual force than licensors;
iii. a licensee would not enter in a licensing agreement unless granted a three-times payback ratio, thus retaining 75% of the profit and investing 25% of them to grant the rights;
iv. the ratio of R&D expenses to profits is within a range of 25% and 33%[222].

Although it is a quick and straightforward method, the profit split method using the 25% rule has been heavily criticized for its crudeness and arbitrariness[223]. Furthermore, there is a lack of clarity as to whether the 25% royalty rate refers to a base tied to gross profit or operating profit, potentially distorting the true intent of the rule of thumb[224]. Nonetheless, the 25% rule has been empirically tested by Smith & Parr, who found that the median royalty rate as a percentage of average licensee's operating profit margin was 26.7% across all the 15 industries analysed in their research[225]. For this reason, the rule of thumb can still be used to determine a reference value, based on which sanity checks can be performed to assess the robustness of the results derived from other intangible valuation methods[226].

[219] Hubscher M, Erhart S. (2021), Intangibles in the World of Trasnfer Pricing, 283-298.
[220] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 278-282.
[221] Ibid.
[222] Razgaitis, (1999), Early-Stage Technologies, 99-102.
[223] Stiroh L., Rapp R., (1998), Modern Methods For the Valuation of Intellectual Property, 817-821.
[224] Parr R., (1993), Intellectual Property Infringment Damages: A litigation Support Handbook, 171.
[225] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 278-282.
[226] Vulpiani M., (2014), Special Cases of Business Valuation, 470-471.

Multi-Period Excess Earnings Method

The Multi-Period Excess Earnings Method (MPEEM) is an income method that value any asset, including intellectual property rights, that contribute to generate earnings. The MPEEM is based on the principle that assets can generate earnings in combination with a group of other assets. When considering the cash flows yielded by a specific product, it would be a flawed assumption to consider the entirety of the cash flows attributable to a specific asset, because multiple assets concur to ensure business operations, such as: workforce, fixed assets, monetary assets, and intangible assets. According to the method, this group of assets, referred as *contributory assets*, are assumed be leased from external sources for which fictitious expenses are charged, in order to allow the exploitation of the leading asset, commonly referred as *primary income generating asset* (PIGA), which is the intangible asset under valuation[227]. In other words, the MPEEM isolates earnings generated by the single intangible asset, by deducting from the firm-wide earnings, the income attributable to contributory assets, thus estimating in a residual way the "excess" earnings produced by the intangible asset under valuation[228]. The residual or excess earnings attributable to the intangible assets are discounted to determine the present value using an appropriate rate of return: ultimately the value of the intangible asset will be equal to the free cash flows traceable only to the intangible asset.

The first step in the MPEEM is to project the relevant revenues of the PIGA over its useful life. Often it is not possible to identify a single primary income generating asset, as maybe two intangible assets could be equally significant in the determination of cash flows, in this case a simultaneous MPEEM can be conducted only if the two stream of revenues can be separated, otherwise problems of circular reference can arise[229]. In the opposite case, the Appraisal Foundation suggests to value the lesser of the two assets with another method, and thus reflect its value on the MPEEM applied to the other primary income generating asset[230]. Once identified the leading asset, its related future revenues and expenses are projected over its useful life based on growth assumptions reflecting historical trends: the RUL of the asset is estimated having consideration of its legal life, technical obsolescence, technological aspects, and market factors, as described in section 3.4.1. The following step is to deduct from the projected revenues and

[227] Hubscher M, Erhart S. (2021), Intangibles in the World of Trasnfer Pricing, 299-320.
[228] Grabowski R., Pratt S., (2014), Cost of Capital: Application and Examples, 757-777.
[229] Hubscher M, Erhart S. (2021), Intangibles in the World of Trasnfer Pricing, 299-320.
[230] The Appraisal Foundation, (2010), 19.

expenses over the useful life of the asset, *the contributory asset charges* (CACs), which are the contribution of other assets in determination of the cash flows generated by the single intangible asset. Under the MPEEM, contributory asset charges are conceived as market rates of return on all the contributory assets, reflecting the theoretical economic charge that should be corresponded to lease them in order to enable the intangible asset to generate income[231].

For the sake of the CACs calculation, it is fundamental to identify the contributory assets which concur to the generation of cash flows referred to the single intangible asset. Gooch (1992) suggests that contributory assets are the group of assets that are not income generating themselves, but rather they support the primary income generating asset[232]. Roland & Kernick provides several examples of contributory assets, such as:

i. Net Working Capital;
ii. fixed Assets;
iii. intangible Assets, such as assembled workforce, non-competition agreements, trademarks, trade names, customer lists, software, technologies, patents[233].

The following step entails the determination of the actual capital charge encumbering on the contributory assets. Contributory asset charges should reflect an appropriate return on the fair value of the assets that a third party would expect in order to lease them to the owner of the primary income generating asset, allowing the latter to generate income from the intangible asset's exploitation[234]. CACs can be either based on the *return on*, which represents the return that an investor would require for an investment in a specific asset, or based on the *return of,* which reflects the economic loss for using the asset, such as the depreciation of the asset[235].

To determine the CACs, it is required to determine the fair value of all the contributory assets and the rate of returns pending on them. The fair value of contributory assets may depend whether the asset is reported on the balance sheet or not. For assets recorded in the balance sheet, such as working capital and tangible assets, the starting point is their book value which may be adjusted to reflect market inputs. In case of not observable market inputs, as in the case of tangible assets, the fair value may be based on the determination of the replacement cost. Finally for intangible

[231] Vulpiani M., (2014), Special Cases of Business Valuation, 464-466; Grabowski R., Pratt S., Cost of Capital: Application and Examples, 757-777.
[232] Gooch L., (1992), Capital Charges and the Valuation of Intangible Assets, Business Valuation Review, 5-21.
[233] Grabowski R., Pratt S., Cost of Capital: Application and Examples, 757-777.
[234] Vulpiani M., (2014), Special Cases of Business Valuation, 464-466.
[235] Ibid.

assets, various method can be applied to determine their fair value, as discussed in this chapter.

For the calculation of the return on the contributory assets, the WACC of the entity may be a good starting point. As discussed in section 3.3.2, assets reported in the balance sheet are characterized by different levels of inherent risk, with monetary assets being the least risky, and intangible assets being the riskiest. The rates of return of each asset should therefore reflect the level of risk embedded, thus a reasonable procedure can be to sum or subtract spreads to the WACC in order to effectively account for excess risks or lower risks of the specific contributory asset with respect to the firm wide risk: for example, working capital is deemed to be less risky than the firm-wide risk, hence it is possible to deduct from the firm-wide cost of capital a spread in order to determine an appropriate rate of return. When determining the rate of return of each contributory asset, it is important to bear in mind that the sum of fair value-weighted returns on all the assets must be equal to the WACC of the company; in other words, the assumptions made in determining the rate of returns of each asset, including the intangible asset under valuation, should lead to the reconciliation of the Weighted Average Return on Assets (WARA) with the WACC.
The excess earnings deriving from the difference between the projected net operating profit after tax through the RUL, and the contributory asset charges will be discounted to determine the present value of the excess earnings: the discount rate used will be identified in a residual way by applying the WACC-WARA reconciliation[236]. Finally, the sum of the presented value of the excess earnings will be combined with the possible tax amortization benefit (TAB), in order to determine the fair value of the intangible asset.

The MPEEM turns out to be particularly useful when valuing an intangible asset that represents a primary income generating asset, and thus the pull of other assets will play a role of contribution in generating its economic benefits. The MPEEM is particularly effective in accurately capturing the value of customer relationships. However, its accuracy depends on the precise estimation of CACs and the asset's RUL, while the business plan must be credible to serve as a valid input for the model.

[236] For more information, please refer to section 3.4.2.

3.5 Alternative Valuation Methods

This section focuses on alternative methodologies that have evolved over time in parallel with more traditional income approaches. These include the real option valuation methods, divided into the Black & Scholes Model and the Binomial Model, and the Monte Carlo method, conceived as a useful tool to perform the valuation of intangible assets.

3.5.1 Real Option Valuation Methods

The real option valuation methods can be employed in order to value intangible assets that give the opportunity, thus the option, to undertake specific investments in order to develop projects that can yield cash flows in the future. Real option valuation methods effectively incorporate the flexibility required by management to develop projects and manage them over time, capturing even the option to defer investments, unlike traditional income-based methodologies, such as the DCF. Real option valuation methods are based on the. The method is based on modelling each investment made by the company as a financial instrument capable of capturing both the downside risks and the upside opportunities associated with uncertainty of the investment[237]. For the sake of the method the financial instrument according to which the investment opportunity is modelled is a call option: if a call option is sufficiently similar to the investment opportunity for the firm, then the value resulting from the call option can yield its economic value[238].
Real options can be identified in any corporate projects that provide the opportunity, but not the obligation, to invest capital and undertake expenditures, enabling the company to potentially benefit from the future economic value generated by the project. The present value of the project's future economic benefits can be analogized to the underlying stock price, while the required investment corresponds to the strike price of a call option. Additionally, the decision-making timeframe aligns with the option's time to expiration period: in essence, it can be justified the assumption according to which the project opportunity can be viewed as a financial call option.

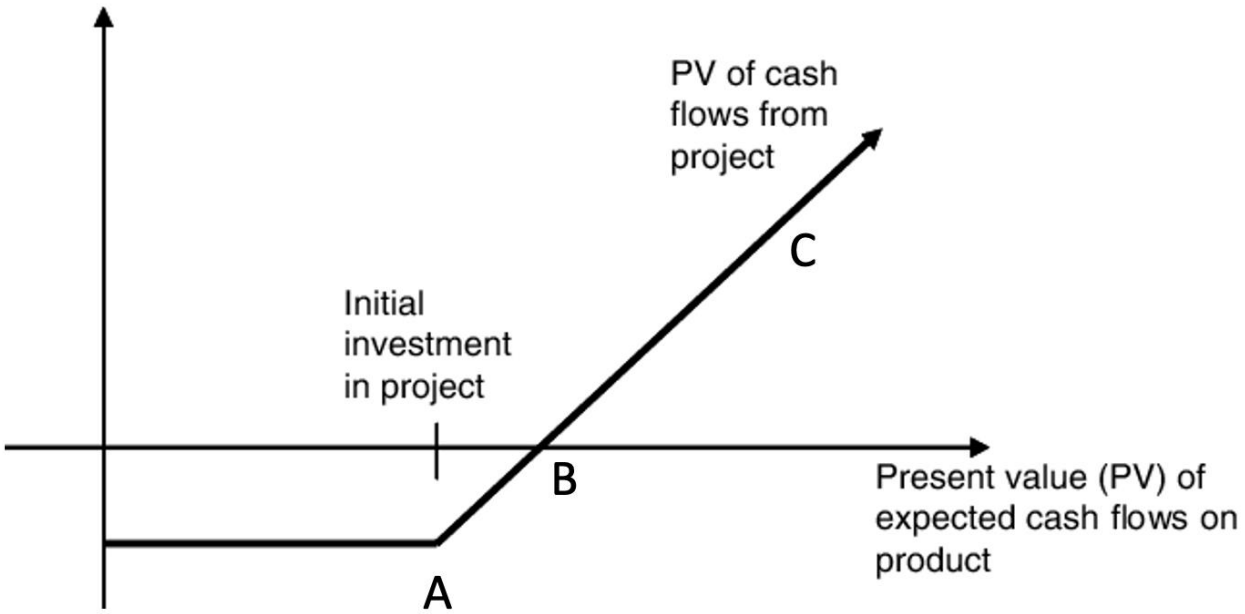
From this paradigm, it can be inferred that any intangible assets that is capable to replicate the characteristics of the aforementioned project, can thus considered as a real option.
Intangible assets that may fall within this category are for instance license, concessions,

[237] Damodaran A, (2006), Damodaran on Valuation, 407-423.
[238] Luehrman T., (1998), Strategy as a portfolio of real options, Harvard Business Review.

undeveloped patents and natural resource investments. The value of these intangible assets can be determined through the valuation of a financial call option with ascribable peculiarities.

Considering an undeveloped patent, such an intangible asset would not generate future economic benefits as of the valuation date unless the firm decides to develop it in the future. This decision represents a development option for the patent, capable of yielding future economic benefits. The company will pursue this option only if the present value of the cash flows generated by the patent in the future exceeds the development cost. In other words, the payoff from exercising the call option must be positive, i.e., the current price of the underlying stock must exceed its exercise price. Meanwhile, the company will have time to decide whether to proceed, a period analogous to the time to expiration of an American call option. As illustrated in Exhibit 3.2, at point A, where the initial investment for developing the patent exceeds the present value of the cash flows, the real option is out of the money. At point B, where the initial investment equals the present value of the patent's future cash flows, the real option is at the money. Finally, at point C, the payoff becomes positive as the present value of the cash flows derived from the patent exceeds the development investment, making the real option in the money. The company will decide to undertake the development of the patent before the expiration of the real option, once the real option becomes in the money.

Exhibit 3.2 *- Payoff Diagram of Product Patent as an Option*



Source: Elaboration based on Damodaran (2006)

For the sake of the real option valuation method, Vulpiani (2014) reports useful conversions from the variables typical of financial options into real options:

i. Stock Price (S) = Present value of a project's operating asset to be acquired
ii. Exercise Price (K) = Investment required to acquire the project assets
iii. Time to expiration (T) = Length of time the investment decision can be deferred
iv. Risk-free rate (r_f) = Time value of money
v. Variance of Stock Returns (σ^2) = Riskiness of the Project Assets[239]

The valuation practice refers to two main valuation methods in order to value real options, which stems from the methods to value financial options, thus configurable as:

i. The Binomial Model;
ii. and The *Black and Scholes Model.*

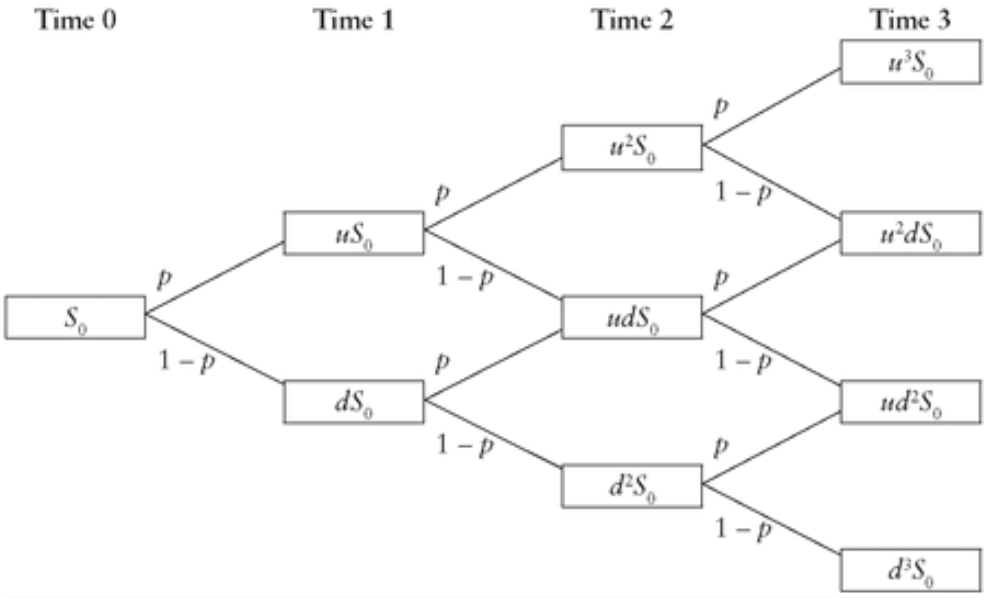
The Binomial Model

The Binomial model, developed by Cox J. C. et al. (1979), is an option pricing model which exploit modes tree analysis from the valuation date of the option to its expiration date. The model is based on a formulation according to which at any given period of time, the underlying stock price can move to one of two prices, thus repeating the process in the subsequent period of time, thereby creating a tree of potential price scenarios[240]: the resulting tree of possible price scenarios is thus called *binomial tree,* as shown in Exhibit 3.3.

It should also be specified that the model developed by Cox is based on simplifying assumptions, including the efficient market hypothesis, implying the absence of arbitrage, a short time to expiration for options, and a reduced intensity of price variations[241].

[239] Vulpiani M., (2014), Special Cases of Business Valuation, 475-477.
[240]Ibid.
[241] Ibid.

Exhbit 3.3 *– Formulation of the Binomial Price Path*



According to the binomial model, the underlying current stock price (S_0) can either move up reaching the price equal to uS_0 with a probability equal to p, or it can decrease thus moving at dS_0 with a probability equal to 1- p. Afterwards, the underlying stock price at time 1 will start at the two different price level previously identified. From this point, for the scenario at time 1 equal to uS_0 the future price can either increase again (u^2S_0) with probability p, or decrease (udS_0) with probability 1- p; whilst for the scenario at time 1 equal to dS_0 the stock price can either increase (duS_0) with probability p, or decrease again (d^2S_0) with probability1-p. The tree of possible price scenarios will continue to branch out for each period t until the expiration of the call option. In this sense, we can summarize as follows:

i. Up factor to the underlying stock price: $u = e^{\sigma\sqrt{\Delta t}}$

ii. Cox-Ross-Rubinstein down factor to the underlying stock price: $d = \frac{1}{u} = e^{-\sigma\sqrt{\Delta t}}$

iii. Neutral risk probability in view of δ (dividend yield) and r (risk-free rate): $p = \frac{e^{(r-\delta)\Delta t} - d}{u-d}$

According to this method, in order to determine the fair value of the call option at time 0, it is necessary to perform the *Backward Induction* procedure. This involves starting from the option's maturity, that is, the terminal leaf of the tree, and determining the value of the option at maturity, which reconciles with its potential payoff:

$V_T = \text{Max}\,(S_t - K, 0)$[242]

where:

V_t= Payoff at expiration

S_t = Stock price at expiration

K = Strike price

At this point, it is possible to determine the value of the option at an earlier stage, which is calculated by discounting the expected value of future up and down branches, weighted by their respective risk-neutral probabilities, as shown in formula 1.16[243]:

$$V_i = e^{-r\Delta T} \times [p \times V_u + (1-p) \times V_d] \quad [1.16]$$

In which:

V_u= value of the option if the underlying price in the following stage increases

V_d= value of the option if the underlying price in the following stage decreases

Finally, the application of the backward induction process will lead to the calculation of the option's value at each preceding node, repeating this process in order to work back to the initial point, represented at time 0, thus determining the current value of the option.

Black and Scholes Model

When the magnitude of price changes becomes small, and the frequency of price changes over time increases, the Binomial Model appears difficult to be applied; in these cases, the binomial model converges with the Black and Scholes. The Black and Scholes model, developed by Fischer Black and Myron Scholes, allows the estimation of the call option value by restraining the amount of input data. The model is based on simplifying assumptions such as the lognormal distribution of the underlying asset prices, which means that the price moves continuously in time with price

[242] Payoff for European Call options. In case of American Call options, the payoff will be equal to $V_t = \text{Max}\,(S_t - K, 0)$.

[243] In case of American call options: $Max\,(e^{-r\Delta T} \times [p \times V_u + (1-p) \times V_d], S_t - K)$.

variation modelled as a random walk, thus implying a geometric Brownian Motion Distribution[244]. Further assumptions are: no arbitrage principle, constant volatility, no dividends, and constant risk-free rate. According to the model a call option value can be determined based on formula 1.17:

$$Value\ of\ the\ call = S\,N(d_1) - Ke^{-rt}N(d_2) \qquad [1.17]$$

In which:

$S =$ Current value of the underlying stock price

$K =$ Strike price of the option

$t =$ Time to expiration of the option

$r =$ risk-free rate with maturity corresponding to the time to expiration of the option

$N =$ Standard normal cumulative distribution function

$$d_1 = \frac{\ln\left(\frac{S}{K}\right)+\left(r+\frac{\sigma^2}{2}\right)t}{\sigma\sqrt{t}}$$

$$d_2 = d_1 - \sigma\sqrt{t}$$

The Black and Scholes formula thus takes into consideration a present value factor (e^{-rt}) which reflects that the exercise price will not be paid until the expiration of the option[245]. Moreover, it derives the option delta (d_1) and the risk adjusted probability of having an option in the money (d_2) from a cumulative standard normal distribution.

Thus, the Black and Scholes Model can be used to value an intangible asset "by creating a portfolio of the underlying asset and the riskless asset with the same cash flows and hence the same cost as the option being valued[246]".

3.5.2 A useful tool: the Monte Carlo Method

The Monte Carlo Method is based on the statistical technique of the *Monte Carlo simulation*, used to model complex data sets whose variables are characterized by uncertainty and randomness. The

[244] In this case under the Brownian Motion Distribution the returns are assumed normally distributed and asset price evolves stochastically over time.
[245] Under the assumption of American call options.
[246] Damodaran A, (2006), Damodaran on Valuation, 407-423.

Montecarlo simulation is a stochastic method that is based on a repeated random sampling to estimate the relative probability distribution of results for any statistical problem[247].
It is crucial to clarify that the Montecarlo method it is not a distinct valuation method; rather it is a technique that can enrich other intangible asset valuation methods, by allowing a set of calculations in order to assess the impact of one or more uncertain variables that may influence the valuation of the intangible asset. For example, an intangible's future cash flows can be analysed by applying certain distribution assumptions regarding the variables impacting the magnitude of the present value of future cash flows. Taking as an example future operating expenses associated with the intangible, to the Monte Carlo simulation can yield insightful data concerning the probability distribution of the future cash flows[248].

Thanks to the repeated random sampling embedded in the simulations, the Monte Carlo Method can yield a range of value of the income parameter that would like to be measured. While income approach assigns a single value to the key input used to determine the value of the intangible asset, like in the case of price premium for the *with and without method;* the Monte Carlo method can give *a* minimum value and maximum value thereby assessing the impact of key valuation inputs to the final value of the intangible asset[249]. Moreover, since the Monte Carlo simulation requires a probability range associated to the variables that are assessed, the method will provide multiple intangible value scenarios giving also the probability of occurrence.
In view of this, the Monte Carlo method may consider several kinds of probability distributions such as:

i. *uniform probability distributions*, assigning the same probability to each value within a range;
ii. *normal distribution*, assigning the highest probability to a central value and decreasing the likelihood when approaching the extreme values;
iii. *triangular distributions*, assigning the highest probability to a single value thereby decreasing the likelihood for values higher or lower than the selected value;
iv. *log normal distributions,* decreasing the probability for values below the maximum value,

[247] Wan X., Li Y., (2021), Evaluation and Management of Intangible Assets of High-Tech Enterprises from the Perspective of Montecarlo and Network Security, Hindawi – Mobile Information Systems.
[248] Beaton N., Sawyer J., (2019), Use of Monte Carlo Simulations in Valuation, Association of Insolvency & Restructuring Advisors, Vol.32, N.2.
[249] Hagelin, T. (2002), A new Method to Value Intellectual Property. American Intellectual Property Law Association Quarterly Journal, Vol.30, 352.

reflecting an asymmetric curve[250].

Based on the chosen probability distribution and the variables to be considered as inputs, the Monte Carlo will perform several simulations of the present value of cash flows arising from the intangible asset: thus, each trial will yield a value of the intangible asset. Finally, each values obtained are reported in a frequency distribution, thereby understanding what is the most likely among the intangible asset values[251].

Therefore, the Monte Carlo method serves as a powerful tool to enhance the precision of primary valuation techniques used for intangible assets, offering insights into whether the range of values derived aligns with the outcomes of the Monte Carlo simulations.

[250] Ibid.
[251] Ibid.

Chapter IV

IP Valuation in the Life Sciences: The Ozempic Case Study

This discussion has empathized the crucial role of intellectual property rights in spurring innovation across sectors and providing competitive advantages for the originating companies. By attracting capital and monetizing exclusive rights through direct exploitation or licensing agreements, intellectual property proves to be a strategic intangible asset, which often cannot be reported in financial statements, especially for those internally generated.

In the Life Sciences sector, patents represent one of the most common intellectual property assets, given their importance in defending and monetizing innovations emerging from the extensive research and development pipelines. This is particularly true for blockbuster drugs, which constitute the value driver for large pharmaceutical companies. Patents provide protection for this source of revenue stream from potential reverse engineering phenomena, through the introduction of generic drugs, thus constituting the complete erosion of the competitive advantage and potentially generating losses on the intense R&D investments.

In the case of blockbuster drugs, the associated patents can be considered the ultimate reason for their staggering profitability thanks to the legal monopoly they confer.

Given their strategic importance, the valuation of patents pertaining to biopharmaceutical companies plays a fundamental role, especially in the context of purchase price allocation, thereby capturing a significant portion of the acquisition price.

In this final chapter, a practical case study is presented on the valuation of the patent for the drug Ozempic, owned by Novo Nordisk, a blockbuster drug from the GLP-1 family that in recent years has driven exponential growth in the biopharmaceutical market.

To this end, since the patent associated with the drug Ozempic is an internally generated asset, the valuation case adopts a simplified premise on which the assessment is conducted within a PPA process with Novo Nordisk as the target of a hypothetical transaction. This premise thus logically justifies the recognition of the patent and consequently, its valuation. It should also be specified that the analysis is exclusively limited to the Ozempic patent and does not encompass all the other identifiable intangible assets, and the assets reported on the balance sheet.

The following describes the U.S. patent associated with Ozempic and discusses the results of its valuation, conducted primarily using the relief from royalty method, and with the 25% rule of thumb, serving as a control method.

4.1 Setting the stage: GLP-1 drugs and the Ozempic patent

Semaglutide, marketed under the trademark Ozempic, is a medication developed by Novo Nordisk that belongs to the *GLP-1 receptor agonist* class, demonstrating effective applications in the treatment of patients with type 2 diabetes. Additionally, it reduces the risk of major cardiovascular events and promotes weight loss.

GLP-1 receptor agonists are drugs used in the treatment of type 2 diabetes, which mimic the action of a class of incretins naturally produced by the human body. Incretins are hormones generated in the gastrointestinal tract, primarily represented by GLP-1 (Glucagon-like peptide 1), produced by the L cells in the ileum/colon, and GIP (Gastric inhibitory peptide), produced by the K cells in the duodenum. These hormones are secreted after meals, particularly GLP-1, and function to regulate blood glucose levels in several ways:

i. Increasing insulin secretion from pancreatic cells;

ii. reducing glucagon secretion (the antagonist of insulin) by inhibiting pancreatic cells;

iii. slowing gastric motility and, consequently, gastric emptying (softening the postprandial blood glucose curve) while reducing appetite;

iv. improving insulin sensitivity[252].

In this regard, GLP-1 receptor analogs represent a class of drugs primarily used in the treatment of type 2 diabetes, reducing the risk of diabetes-related complications such as cardiovascular diseases, kidney damage, and neuropathies, additionally having positive effects on weight reduction. These benefits are increasingly recognized within the healthcare field and now hold a prominent place in international recommendations and guidelines for the treatment of type 2 diabetes throughout the course of the disease[253]. he success of GLP-1 receptor analogs compared to other common anti-hyperglycemic drugs, such as insulin, stems from their effectiveness in managing cardiovascular events related to type 2 diabetes, their promotion of weight loss, and the

[252] Nauck M.A., Quast D.R., Wefers J., Meier J. J., (2020), GLP-1 receptor agonists in the treatment of type 2 diabetes e state-of-the-art, Molecular Metabolism.
[253] Gallwitz B., Giorgino F., (2021) Clinical Perspectives on the Use of Subcutaneous and Oral Formulations of Semaglutide, Frontiers in Endocrinology.

reduced frequency of drug administration[254]. Regarding the last point, as shown in Exhibit 4.1, GLP-1 drugs—except for Lixisenatide, Exenatide, and Liraglutide—are characterized by a reduced frequency of administration and dosage compared to traditional insulin.

Exhibit 4.1 *– Types of GLP-1 receptor analogs and their dosage regimens.*

	Exenatide	Lixisenatide	Liraglutide	Exenatide ER	Dulaglutide	Semaglutide	
Route	Subcutaneous	Subcutaneous	Subcutaneous	Subcutaneous	Subcutaneous	Subcutaneous	Oral
Frequency	Twice daily	Once daily	Once daily	Once weekly	Once weekly	Once weekly	Once daily
Timing of administration	Within 60 mins of the morning and evening meal	Within 60 mins of any meal (preferably the same meal each day)	Any time (independent of meals) but preferably the same time each day	Any time of day, with or without meals	Any time of day, with or without meals	Any time of day, with or without meals	On an empty stomach 30 mins before eating, drinking, or taking other oral medications
Dosage regimens	Starting: 5 µg	Starting: 10 µg	Starting: 0.6 mg	No up-titration	No up-titration	Starting: 0.25 mg	Starting: 3 mg
	Maintenance: 10 µg	Maintenance: 20 µg	Maintenance: 1.2 mg & 1.8 mg	Maintenance: 2 mg	Maintenance: 0.75 mg for monotherapy or 1.5 mg as add-on (a starting dose of 0.75 mg may be used in vulnerable patients)	Maintenance: 0.5 mg & 1.0 mg	Maintenance: 7 mg & 14 mg

Source: Gallwitz B., Giorgino F., (2021), Clinical Perspectives on the Use of Subcutaneous and Oral Formulations of Semaglutide, Frontiers in Endocrinology.

Among the main GLP-1 analog drugs available on the market are: *Semaglutide*, marketed as Ozempic and Wegovy by Novo Nordisk*; Dulaglutide*, known as Trulicity by Eli Lilly; Liraglutide, marketed as Victoza by Novo Nordisk; *Exenatide*, recognized under the brand names Byetta and Bydureon by Amylin Pharmaceuticals; *Albiglutide*, known as Eperzan by GlaxoSmithKline; *Lixisenatide*, marketed as Lyxumia; and *Tirzepatide*, branded as Mounjaro by Eli Lilly.

In recent years, the use of some of these drugs has significantly expanded beyond the treatment of type 2 diabetes, thanks to their secondary effect of promoting weight loss. In the United States, *Semaglutide* by Novo Nordisk and *Tirzepatide* by Eli Lilly have received approval from the Food and Drug Administration (FDA) for use as a specific therapy for obese patients. This approval has greatly broadened the potential patient base. Moreover, there has been growing demand for their use—despite discouragement from health authorities—among individuals without metabolic disorders who are interested in rapid weight loss as an effective alternative to dietary regimens.

This situation, combined with the inability to rapidly adjust production capacity, has led to periodic shortages of these drugs on the market, causing difficulties for diabetic patients, who are the primary intended recipients of these medications. The prospects for the use of GLP-1 drugs in

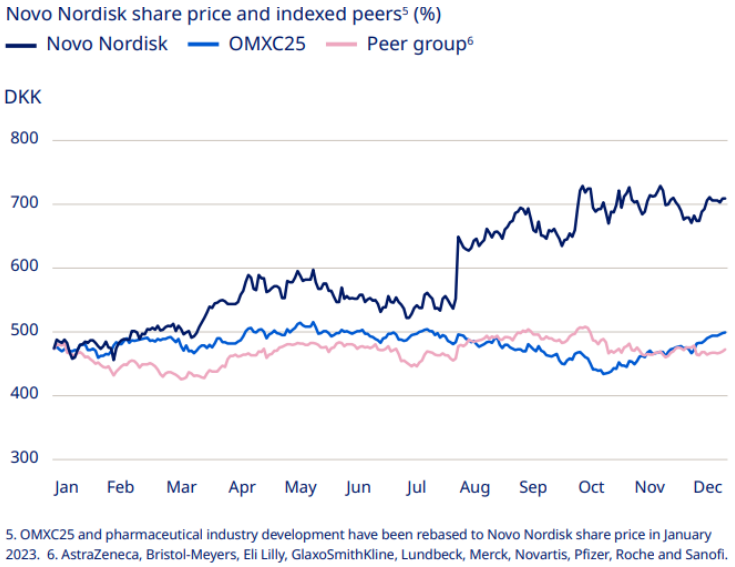
[254] El Aziz et. Al. (2016), A meta-analysis comparing clinical effects of short- or long-acting GLP-1 receptor. agonists versus insulin treatment from head-to-head studies in type 2 diabetic patients, Diabetes Obes Metab. 2017.

weight-loss treatments indicate significant potential, which identifies a potential market with high growth rates, as already highlighted in the second chapter.[255]

Novo Nordisk A/S, (the Company), is the owner of the Semaglutide patent (Ozempic) which is one of the most widely used drugs in the GLP-1 class.
Founded in 1923 and headquartered in Denmark, it is controlled by the Novo Nordisk Foundation, which holds the majority of voting rights at general meetings and is listed on the Copenhagen Stock Exchange and the NYSE. Novo Nordisk operates globally, with a presence in 80 countries and a strong focus on diabetes care, while also engaging in other therapeutic areas such as obesity, hemophilia, endocrine disorders, and hormone therapy. The company is a leader in, producing medications including insulins and GLP-1 analogs, which collectively serve over 40 million patients worldwide. Although not its primary focus, Novo Nordisk also invests in cardiovascular disease treatments, particularly in combination with diabetes and obesity therapies.
The Company the global market leader of type 1 and type 2 diabetes care, holding as of the fiscal year 2023, the 33.8% of the market share. Novo Nordisk registered sustainable growth thanks to the success of GLP-1-based products, primarily Ozempic and Rybelsus, both in the North American market and internationally.
Ozempic is the world's best-selling type 2 diabetes drug in the once-weekly subcutaneous injection category. At the same time, the company's other oral GLP-1 therapy, Rybelsus, is gaining traction by offering needle-averse type 2 diabetes patients an effective non-injection treatment.
Demand for these two products has reached unprecedented levels in recent years, and Novo Nordisk, as of December 2023, reports a 54.8% share of the GLP-1 market. As depicted in Exhibit 4.2, the strong adoption of GLP-1 drugs, and specifically the success of Ozempic in treating type 2 diabetes, as well as treating collateral cardiovascular conditions and enhancing weight loss, lead to a surge in the share price of Novo Nordisk, thereby overperforming peers during the fiscal year 2023.

[255] Please refer to section 2.2.

Figure 4.2 *- Share performance of Novo Nordisk compared to Peers.*



5. OMXC25 and pharmaceutical industry development have been rebased to Novo Nordisk share price in January 2023. 6. AstraZeneca, Bristol-Meyers, Eli Lilly, GlaxoSmithKline, Lundbeck, Merck, Novartis, Pfizer, Roche and Sanofi.

Source: Novo Nordisk 2023 Annual Report.

Ozempic (*semaglutide*) received its first approval for medical use by the FDA in the United States for the treatment of type 2 diabetes on December 18, 2017. Subsequently, the medication was also approved in other countries, as the EMA granted the approval on February 6, 2018, allowing its commercialization in European Union countries, while in March of the same year Ozempic was approved in Japan, thereby extending the availability globally. Novo Nordisk's GLP-1 drugs have experienced significant growth, with a CAGR of 38.3% for the period 2019-2023, driven by the sales of Ozempic, which recorded a staggering sales growth with a CAGR of 70.3%, reaching global sales of $14.2 billion. In parallel, as shown in Exhibit 4.3, Rybelsus has gained market share, reaching approximately $2.8 billion in global sales, while Victoza has experienced a decline since 2019, partly due to the patent cliff.

Exhibit 4.3 *– Novo Nordisk's Global GLP-1 Sales*

Global GLP-1 Products Sales Novo Nordisk

Ozempic, Rybelsus, Victoza

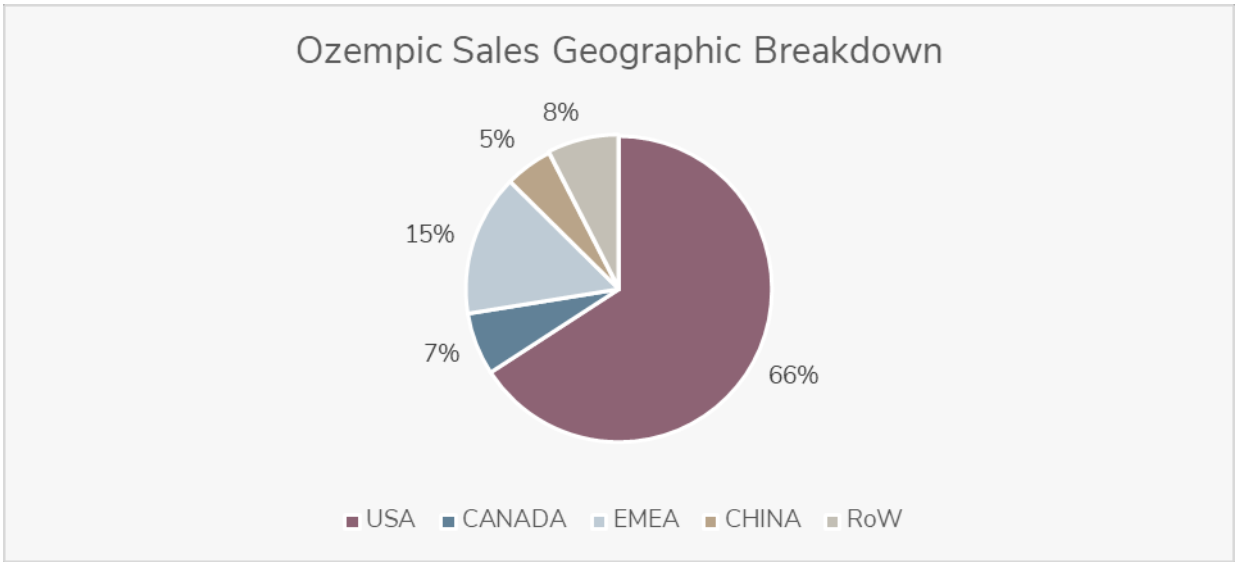
Million of Dollars

	FY2019	FY2020	FY2021	FY2022	FY2023
Rybelsus	8	308	740	1,623	2,781
growth (%)		3999%	140%	119%	71%
Ozempic	**1,688**	**3,486**	**5,155**	**8,585**	**14,195**
growth (%)		**107%**	**48%**	**67%**	**65%**
Victoza	3,294	3,081	2,303	1,770	1,285
growth (%)		-6%	-25%	-23%	-27%
Total GLP-1	**4,989**	**6,875**	**8,198**	**11,979**	**18,260**

Source: Novo Nordisk Annual Reports

GLP-1 medications represent a strategic operating segment for Novo Nordisk, weighting roughly 53% of the overall revenues, with Ozempic standing as a strategic cornerstone of the Company's drug portfolio with sales being equal to 41.1% of the overall revenues. As depicted in Exhibit 4.4, the U.S. market represents the most critical source of revenue streamline related to Ozempic, consisting of 66% of the global sale of Semaglutide. This is undoubtedly attributable to the high concentration of diabetic patients in the United States, coupled with the premium pricing that characterizes the American market for all specialized medications. On the other hand, while EMEA represents the second largest market for Ozempic, accounting for 15% of the global Ozempic sales, Canada Rest of the World and China account for 7%, 8% and 5% of the Ozempic's sales respectively.

Exhibit 4.4 *- Geographic Breakdown of Ozempic Sales*



Source: Personal Elaboration based on Novo Nordisk Annual Report

The competitive advantage of Ozempic lies in the patent, that protects its formulation and application for type 2 diabetes treatments, from reverse engineering by potential generic competitors. Additionally, by virtue of its patent rights, Novo Nordisk is able to charge a premium price in the United States, amounting on average to $936.0, as of 2023. The U.S. patent associated with Ozempic is identified as US 8129343, filed by Novo Nordisk in March, 2006, titled "Acylated GLP-1 Compounds". The patent US 8129343 pertains to GLP-1 compounds and their therapeutic uses, envisaging claims that relate to the compound "semaglutide" and all the pharmaceutical compositions containing semaglutide (claims 1-2 and 4-5), specifying methods of treating type 2 diabetes that include administering an effective amount of semaglutide to a patient. These patent claims were further enhanced by U.S. Patent 10335462 in July 2019, which claims the administration of Semaglutide once a week for the treatment of type 2 diabetes.

The FDA approved the New Drug Application (NDA) No. 209637 for Ozempic for subcutaneous injections to treat type 2 diabetes, in the dosages of 2 mg/3 ml (0.68 mg/ml), 2 mg/1.5 ml (1.34 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml (2.68 mg/ml). The sales of Ozempic in the United States are experiencing significant expansion, thanks to its effectiveness in treating type 2 diabetes, as well as its weight loss effects, with the latter leading to a surge in prescriptions even for individuals not affected by type 2 diabetes. As shown in Exhibit 4.5, Ozempic sales in the United States as of 2023 stands at $9.3 billion, having almost quintupled since 2019, growing at a CAGR of 59.6%, thus currently being one the most profitable blockbuster drugs in the American territory.

Exhibit 4.5 *– Novo Nordisk's U.S. GLP-1 Sales*

Novo Nordisk GLP-1 Sales in the U.S.

Ozempic, Rybelsus, Victoza

Million of Dollars

	FY2019	FY2020	FY2021	FY2022	FY2023
Rybelsus	8	300	649	1,151	1,640
growth (%)		3896.4%	116.3%	77.4%	42.5%
Ozempic	**1,442**	**2,736**	**3,544**	**5,568**	**9,344**
growth (%)		**89.8%**	**29.5%**	**57.1%**	**67.8%**
Victoza	2,135	1,856	1,228	920	536
growth (%)		-13.1%	-33.8%	-25.1%	-41.8%
Total GLP-1	**3,584**	**4,892**	**5,421**	**7,639**	**11,520**

Source: Novo Nordisk Annual Reports

Despite recent trends indicating the use of Ozempic as a weight-loss medication for individuals not affected by type 2 diabetes, the drug is approved in the United States solely and exclusively for the continuous treatment of type 2 diabetes conditions. Notwithstanding this, Novo Nordisk has recently initiated a cycle of clinical trials in order to demonstrate the effectiveness and safety of administering Ozempic purely as a weight loss drug. In this regard, Novo Nordisk has developed a new drug called Wegovy, based on long-acting GLP-1 peptides, in order to provide the market with treatment for weight loss.

The American patent for Ozempic, as shown in Exhibit 4.6, is expected to expire on January 1, 2032, while the patents for Europe, Japan, and China are expected to expire in 2031 and 2026, respectively. Therefore, Novo Nordisk still has 8 years to exploit the monopoly rights of Ozempic in the United States.

Exhibit 4.6 *– Novo Nordisk's Patents Expiration status.*

DIABETES

Product	US	China	Japan	Europe[2]
Human insulin and Modern insulins[3]	Expired	Expired	Expired	Expired
Victoza®[4]	Expired	Expired	Expired	Expired
Tresiba®	2029	2024	2027	2028
Ryzodeg®	2029	2024	2024[5]	2028
Xultophy®	2029	2024	2024[5]	2028
Fiasp®	2030[6]	2030[6]	2030[6]	2030[6]
Ozempic®	2032	2026	2031	2031
Rybelsus®	2032	2026	2031	2031

Source: Novo Nordisk Annual Reports

The prominence of Ozempic in the American market imbues its intellectual property, such as the trademark and associated patent, with strategic importance to ensure competitive advantages over competitors. For this reason, conducting a valuation of the American patent associated with Ozempic can be useful in order to capture its future economic benefits along its remaining useful life: the aim in the following section is to determine the fair value of the U.S. patent, which is not shown on the Company's balance sheet, as it is an internally generated intangible asset, in accordance with IAS 38.

4.2 Valuation of the Ozempic U.S. Patent

The research objective of this paper is to contribute to empirical valuation by identifying a valuation approach to be employed in the case of intellectual property rights, such as a patent, associated with a blockbuster drug, characterized by a significant limitation in the available public data. As previously mentioned, the object of the evaluation is the American patent associated with Novo Nordisk's drug Ozempic, a blockbuster drug that has revolutionized the treatment of type 2 diabetes, as well as being a potential remedy for weight loss. Considering the nature of the asset under assessment, namely a pharmaceutical patent, which often represents the subject of licensing agreements in the sector, and given the limited availability of public data, the Relief from Royalty Method was selected as the method best capable of representing the intrinsic value of the American patent for Ozempic. The reliability of this method was verified through the application of the Rule of Thumb method based on the 25% profit split; a methodology historically used for determining royalty rates in licensing agreements.

Before proceeding with the description of the valuation analysis of the American patent of Ozempic, it is necessary to provide a premise that justifies the valuation of the intellectual property itself. Since the patent in question is an internally generated intangible asset, an impairment valuation would be meaningless, as the asset is not reported in the balance sheet. Therefore, within the framework of a Purchase Price Allocation, assuming Novo Nordisk's Diabetes and Obesity Care Business Unit as a target of a hypothetical transaction, it is possible to justify the recognition of such internally generated intellectual property and thus carry out the valuation of its fair value. The analysis is based on the estimation of the fair value of the American patent alone, and not the entirety of the intangible assets characterizing this business unit. The fair value of the patent in question is appraised as of December 31, 2023 thus using the Relief from Royalty Method as primary methodology, and the Rule of Thumb considering a 25% profit split, as a control methodology.

The description of the analysis and the results of the valuation of the American Patent of Ozempic are summarized below.

4.2.1 Relief from royalty: projection of Future Economic Benefits

The U.S. patent of Ozempic relates to the application of GLP-1 long active peptide, namely Semaglutide, for treating type 2 diabetes condition through weekly subcutaneous injections. For this reason, the analysis does not incorporate any direct market factors arising from the consumption trend of Ozempic exclusively for weight loss purposes. Therefore, exclusively diabetes type 2 patients are considered as the target consumers for this analysis, in line with the claims of the Patent and the marketing approval of the FDA. The American patent of Ozempic is set to expire on January 1, 2032, therefore its Legal Life is equal to 8 years as of December 31, 2023 (the Valuation Date). Since the future economic benefits of patents are anchored to the legal rights therein, the Remaining Useful Life (RUL) of the U.S. Patent is assumed to be equal to its Legal Life: therefore, the RUL is assumed to be equal to 8 years.
In order to carry out the primary valuation methodology, the relief from royalty method, it is necessary to project the future revenues attributable to the U.S. patent. In this case, a simplifying assumption is taken; the revenues arising from the sales of Ozempic in the American territory are assumed to be entirely attributable to the U.S. patent, due to its premium pricing rights and its protection from reverse engineering of generic competitors. In addition, this assumption takes into account the territoriality of the legal protection of the patent under evaluation, which therefore applies solely and exclusively to the USA, as Novo Nordisk holds different patent rights for Europe and Japan. Finally, it is important to highlight that the American patent is associated with medical applications authorized by the FDA, thus valid only for the USA, since the European patent for Ozempic has slightly different authorizations issued by the EMA: therefore, the above assumption is also consistent with the medical authorizations issued by the different regional authorities. .

According to a recent study, carried out by Peterson KFF Center, in 2023 Ozempic was marketed in the United States at an average price of $ 936.0, over 5 times more with respect to Japan, in which Ozempic is marketed at an average price of $ 169.0[256]. This price relates to a monthly treatment for type 2 diabetes, and since diabetic patients need continuous treatment, they need subcutaneous injections of Ozempic every week of the year: thus, the price of a yearly treatment stands as of 2023 at $ 11,232.
Dividing the sales of Ozempic as of 2023 in the United States, being equal to $ 9.34 billion, by the

[256] Peterson-KFF Health System Tracker, (2023), How do prices of drugs for weight loss in the U.S. compare to peer nations' prices?.

average price of yearly treatments, it is plausible to find the number of yearly treatments of Ozempic among American type 2 diabetic patients, thus equal to 831,927 yearly treatments. In this case, occasional consumers are not considered, and therefore all treatments are assumed to be of a continuous nature. The costs of certain treatments in America can be covered if enrolled in the Medicare Plan D insurance plan, which currently does not benefit from discounted prices for Ozempic. Based on statistics from the Centers for Medicare & Medicaid Services (CMS), about 26% of the enrollees in Medicare Plan D have benefited from access to diabetes medications. Consequently, for the purposes of the analysis, 26% of such treatments are assumed to be covered by Medicare Plan D for the entire projection period[257].

For the prospective revenues attributable to the Patent the average price of yearly treatments not covered by Medicare Plan D is assumed to remain constant over the entirety of the forecast period. In force of the Inflation Reduction Act (IRA), Ozempic was recently selected among the blockbuster drugs eligible for price negotiation with Medicare Plan D. The Company is currently under negotiation with Medicare, and by 2027 Ozempic will be available at a discounted price for Medicare Plan D enrollees.

Therefore, the price for yearly treatments covered by Medicare Plan D is held constant until FY2027, the year in which the effect on price negotiation will occur, to be subsequently reduced and held constant until the last year of the RUL. In order to determine the discount on Ozempic for Medicare Plan D enrollees, an analysis of the discounts on the previous 10 selected drugs by the government was carried out. As depicted in Exhibit 4.7, blockbuster drugs that were marketed at a premium price were affected by significant discounts, with a maximum discount of 79% as for Januvia's price, and a minimum discount of 38% related to Imbruvica.

[257] CMS.gov database.

Exhibit 4.7 *– Medicare Plan D Negotiated Price of the first 10 selected drugs*

Medicare D price negotiations first 10 selected drugs

Application of the negotiated price expected on 2026

Dollars

Drug Name	Drug company	Agreed Price	Price @2023	Discount
Januvia	Merck	$113.0	$527.0	-79%
Fiasp	Novo Nordisk	$119.0	$495.0	-76%
Farxiga	AstraZeneca	$178.5	$556.0	-68%
Enbrel	Immunex	$2,355.0	$7,106.0	-67%
Jardiance	Boehringer	$197.0	$573.0	-66%
Stelera	Janssen Bio	$4,695.0	$13,836.0	-66%
Xarelto	Janssen Pharm	$197.0	$517.0	-62%
Eliquis	Bristol Myers Squibb	$231.0	$521.0	-56%
Entresto	Novartis	$295.0	$628.0	-53%
Imbruvica	Pharmacyclinics	$9,319.0	$14,934.0	-38%
Average				**-63%**
Median				**-66%**

Source: Elaboration based on CMS.gov.

In order to determine the price effect of negotiations on Ozempic price for Medicare Plan D enrollees, the average discount for the first 10 selected drugs, equal to 63%, was applied to the average price for yearly treatments, determining a price of $ 4,155.8 for yearly treatments covered by Medicare Plan D: this price was held constant until the final year of the Remaining Useful Life of the Patent.

Currently, Novo Nordisk states that its production capacity is increasing to ensure as much medical supply as possible to type 2 diabetic patients; in light of a rapidly growing demand, thus it is reasonable to expect similar growth levels of Ozempic in the U.S. registered in recent years. For this purpose, yearly treatments of Ozempic in the United States are projected in fiscal year 2024 at the historical CAGR of FY2021-FY2023 equal to 59.6%, thereby capturing the upward trajectory of the sales in recent years. Beyond FY2024 the growth rate is assumed to assumed to decrease linearly reaching a long-term growth rate equal to 2.5% in FY2027. The long-term growth rate of yearly treatments was assumed to be equal to the expected CAGR of type 2 diabetes patients in the United States, from 2021 to 2040. According to Population Health Metrics the American diabetic population is expected to increase severely in 2040, reaching a total number of 47.86 million of U.S. citizens, as illustrated in Exhibit 4.8.

Exhibit 4.8 *– Expected American diabetic population for 2040.*

Projection of the future number (in millions) and percent (%) prevalence of US adults with diagnosed diabetes, by age group for selected years 2014–2060

Population (Millions)					
Age group (in years)					
	18–44	45–64	65–74	> = 75	Total
2014	2.86	10.27	5.51	3.67	22.31
	(2.67, 3.07)	(9.79, 10.77)	(5.28, 5.75)	(3.46, 3.89)	(21.19, 23.48)
2020	3.84	12.1	8.01	5.32	29.27
	(3.53, 4.21)	(11.54, 12.71)	(7.70, 8.34)	(5.07, 5.60)	(27.84, 30.86)
2030	5.01	13.67	10.92	10.11	39.71
	(4.45, 5.68)	(12.72, 14.71)	(10.34, 11.57)	(9.58, 10.73)	(37.09, 42.69)
2040	5.32	16.42	11.22	14.89	47.86
	(4.69, 6.08)	(15.11, 17.87)	(10.50, 12.00)	(14.00, 15.92)	(44.30, 51.87)

Source: Lin J. et. al, (2018), Projection of the future diabetes burden in the United States through 2060, Population Health Metrics, 16;9.

The latest available data concerning the number of Americans with diagnosed diabetes is dated 2021, which is equal to 29.7 million of people. Furthermore, type 2 diabetes is the most common form of diabetes among American citizens, standing at an average incidence of 90% of the total diabetic population[258]. Therefore, it is plausible to derive the implied number of current and future Americans with diagnosed type 2 diabetes by applying this percentage to the current diabetic population, equal to 26.7 million of people and expected diabetic population, equal to roughly 43 million of people. In this case, the prospective CAGR from 2021 to 2040 for Americans diagnosed with type 2 diabetes is equal to 2.54 %.

This CAGR was used to project yearly treatments from FY2027 until FY2031 in order to capture the yearly treatments of Ozempic in steady state conditions, where the growth of treatments is a function of the increase in type 2 diabetes population.

As a result, by multiplying the average price of yearly treatments by the projected portion of yearly treatments not covered by Medicare Plan D, it is possible to obtain the projected revenues not arising from Medicare. In parallel, by multiplying the average price for yearly treatments covered by Medicare Plan D, $ 11,232 until FY2027 and $ 4,155.8 onwards, by the projected yearly treatments covered by Medicare Plan D, it is feasible to derive the revenues arising from Medicare

[258] Lancet, (2023) Global, regional, and national burden of diabetes from 1990 to 2021, with projections of prevalence to 2050: a systematic analysis for the Global Burden of Disease Study 2021, 203-34.

Plan D. The sum of the two revenues streams yields the projected revenues from Ozempic sales from FY2023 to FY2031, which in this case overlaps with the revenues attributable to the American Patent. Based on the projections, the revenues attributable to the American Patent for FY2024 are equal to $ 14.91 billion, thereby growing at a CAGR of 7.1% until FY2031, reaching $ 24.16 billion. The projected revenues of the analysis are shown in Exhibit 4.9[259].

Exhibit 4.9 *– Projections of the revenues attributable to the American Patent of Ozempic along the RUL.*

		FY2023 Historical	FY2024 Projected	FY2025 Projected	FY2026 Projected	FY2027 Projected	FY2028 Projected	FY2029 Projected	FY2030 Projected	FY2031 Projected
Yearly Treatment Expected Price	$0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011
Yearly Treatment Price under Medicare D	$0.004					0.004	0.004	0.004	0.004	0.004
Expected yearly treatments (Total)		831,927	1,327,428	1,865,765	2,267,817	2,325,489	2,384,626	2,445,268	2,507,452	2,571,217
Growth rate (%)			59.6%	40.6%	21.5%	2.5%	2.5%	2.5%	2.5%	2.5%
of which Treatments under Medicare D		216,301	345,131	485,099	589,633	604,627	620,003	635,770	651,937	668,516
of which Treatments excluding Medicare D		615,626	982,297	1,380,666	1,678,185	1,720,862	1,764,623	1,809,498	1,855,514	1,902,700
Revenues from Medicare D		2,429	3,877	5,449	6,623	2,519	2,583	2,648	2,716	2,785
Revenues excluding Medicare D		6,915	11,033	15,508	18,849	19,329	19,820	20,324	20,841	21,371
Revenues from yearly treatments		**9,344**	**14,910**	**20,956**	**25,472**	**21,847**	**22,403**	**22,973**	**23,557**	**24,156**
Growth rate (%)			59.6%	40.6%	21.5%	-14.2%	2.5%	2.5%	2.5%	2.5%

Source: Personal Financial Model

4.2.2 Relief from royalty: The discount rate

In order to carry out the relief from royalty method, it is fundamental to identify an appropriate discount rate to apply to the future economic benefit arising from the patent ownership. In valuing intellectual property, specifically in hypothesis of PPA, the ideal approach to determine the appropriate discount rate is represented by the WACC-WARA reconciliation, under which the weighted average return on of each asset, weighed for its portion of firm's enterprise value, should reconcile with the firm-wide WACC. In this case, finding the step-up and step-down factors for each contributory asset, in order to determine its fair value, was deemed not feasible based on the information available, and the risk of making assumptions too far from reality was high since the rates of return on monetary assets and tangible assets were equally difficult to estimate due to the available information. Therefore, the key simplifying assumption, in order to carry out the valuation of the patent, was to consider the levered cost of equity as a proxy of the patent rate of return.

[259] For more information, please refer to Annex B

This approach is consistent with respect to the findings of Stegink, Schauten, and Graaff, who demonstrated empirically that the cost of equity is a better surrogate measure of the discount rate of intangible assets, with respect to the firm-wide WACC and the unlevered cost of equity. This approach grants the possibility to derive directly the cost of capital of the intellectual property asset under valuation, while accounting for a step-up factor with respect to the Unlevered Cost of Equity, as a direct consequence of the Modigliani-Miller's second proposition: the cost of equity for a levered firm is equal to the cost of equity of unlevered firm plus an additional premium for financial risk. At the same time, the cost of equity hereby considered will be higher than the firm-wide WACC, since the effect of interest tax shields is not taking into account and as the lower cost debt does not impact the cost of equity: therefore, the discount rate of the U.S. Patent will be higher with respect of the firm-wide WACC, thereby underlying the higher inherent risk of the asset with respect to the average risk of other assets. Therefore, the discount rate of the U.S. patent was assumed to be equal to Novo Nordisk's levered cost of equity.

In order to determine firm's levered cost of equity, the expanded Capital Asset Pricing Model (expanded CAPM) has been used, according to which the firm's cost of equity can be derived as depicted by formula 4.1:

$$K_e = R_f + \beta * (ERP) + SP + CRP + A \qquad [4.1]$$

In which:

$R_f =$ Risk-free rate of a government bond's yield of the same currency as the cash flows

$\beta =$ Levered Adjusted Beta which reflect for the systematic risk of the firm

$ERP =$ The excess return over risk-free investments that an average investor expects to invest in equities over risk-free securities for mature equity markets

$SP =$ Additional premium over CAPM that reflects the higher risk in investing in smaller

companies compared to larger companies[260]

$CRP =$ Equity premium adjustment to account for the additional inherent risk in investing in a security related to a country exposed to country risk

$A =$ Additional premium over CAPM that reflects the idiosyncratic risk arising from investments stocks that are exposed to specific industry factors or characterized by unique risks of the very same firm's business operations.

In this case, the future cash flows to be discounted are presented in US dollars, therefore by adhering to the consistency principle, the risk-free rate selected was assumed to be equal to the spot rate of the 10-Year U.S. Treasury Bond as of December 31, 2023: the maturity selected for the yield of the risk-free security aligns to the length of the forecast period, which in turn is based on the RUL of the U.S. Patent. As of the Valuation Date the spot rate of the 10-Year U.S. Treasury Bond was equal to 4.58%. Novo Nordisk's Beta was derived by applying the Bottom-Up approach, in order to capture industry Beta and account for the impact of financial leverage, which in this case turns out to be forward looking, as the leverage ratio was implied by the industry average.

Moreover, this choice can be justified by the fact that Novo Nordisk's stock was characterized in the last year by a significant surge in its price, increasing potentially the noise of historical returns when performing the linear regression. Thus, the first step that was carried out was the selection of the panel of comparable companies for Novo Nordisk. The criteria of comparability were based on market cap size, size of the revenues, magnitude of EBITDA margin, and business fit. The business fit criterion was based on the comparability of the firm's operation concerning the production of GLP-1 medications and medications for diabetic care. The selected panel of comparable companies is reported in Exhibit 4.10:

[260] Banz R. (1981) in his paper "The Relationship Between Return and Market Value of Common Stocks" found the empirical existence of higher risk adjusted returns for smaller companies with respect to bigger companies, attributing this premium to a size effect.

Exhibit 4.10 *– Panel of comparable companies for Novo Nordisk*

Company	Primary Ticker	Currency	Levered Beta (Raw Beta)	Levered Beta (Beta Adusted)
Eli Lilly and Company	NYSE:LLY	USD	0.60	0.73
GSK plc	LSE:GSK	GBP	0.61	0.74
Sanofi	ENXTPA:SAN	EUR	0.64	0.76
Merck KGaA	XTRA:MRK	EUR	0.38	0.59
Pfizer Inc.	NYSE:PFE	CHF	0.79	0.86
Bristol-Myers Squibb Company	NYSE:BMY	USD	0.63	0.76
Johnson & Johnson	NYSE:JNJ	USD	0.47	0.64
AbbVie Inc.	NYSE:ABBV	USD	0.48	0.65
Takeda Pharmaceutical Company Limited	TSE:4502	USD	0.42	0.61
AstraZeneca PLC	LSE:AZN	EUR	0.79	0.86

Source: Personal Financial Model

For each comparable company the historical levered beta (Raw Beta) was sourced, and then adjusted to reflect a forward-looking beta, using the Blume Formula reported in formula 4.2:

$$\beta_{adjusted} = \frac{2}{3} \times \beta_{raw} + \frac{1}{3} \times 1 \qquad [4.2]$$

Subsequently, it was determined the capital structure for each comparable company, thus determining each market value of equity, and the value of Net Debt, in order to derive each stock's leverage ratio (D/E), together with the corporate tax rate levying on each firm's operations. Each adjusted levered Beta was unlevered in order to sterilize the impact of the financial structure, using the Hamada Formula reported in Equation 4.3:

$$\beta_{unlevered} = \frac{\beta_{levered}}{\left[1 + \frac{D}{E} \times (1-t)\right]} \qquad [4.3]$$

The results of the process of de-levering each Beta are reported in Exhibit 4.11, in the end obtaining a industry average Unlevered Beta of 0.51 and median of 0.53, with an industry average target leverage (D/E) of 22.1%, calculated as the average of the single comparable companies' D/E.

Exhibit 4.11 *– Unlevered Betas and Target Industry Average D/E*

Company	Levered Beta (Beta Adusted)	Debt-to-Total Capital (Wd) = (Md/TC)	Equity-to-Total Capital (We) = (Me/TC)	Leverage Ratio (D/E)	Effective Tax Rate (t)	Unlevered Beta (Bu)
Eli Lilly and Company	0.73	4.3%	95.7%	4.5%	25.8%	0.58
GSK plc	0.74	16.6%	83.4%	19.9%	25.0%	0.53
Sanofi	0.76	8.2%	91.8%	8.9%	25.8%	0.60
Merck KGaA	0.59	10.8%	89.2%	12.1%	29.9%	0.35
Pfizer Inc.	0.86	27.9%	72.1%	38.7%	25.8%	0.61
Bristol-Myers Squibb Company	0.76	21.9%	78.1%	28.1%	25.8%	0.52
Johnson & Johnson	0.64	2.0%	98.0%	2.0%	25.8%	0.46
AbbVie Inc.	0.65	14.9%	85.1%	17.5%	25.8%	0.42
Takeda Pharmaceutical Company Limited	0.61	43.6%	56.4%	77.3%	29.7%	0.27
AstraZeneca PLC	0.86	10.2%	89.8%	11.4%	25.0%	0.73
Industry Average		**16.1%**	**84.0%**	**22.1%**	**26.5%**	**0.51**
Industry Median		**12.8%**	**87.2%**	**14.8%**	**25.8%**	**0.53**

Source: S&P Capital IQ and Personal Financial Model

Finally, the Beta for Novo Nordisk was derived by re-levering the industry's median unlevered Beta, equal to 0.53, given the presence of high variability in the data set, and the industry average target financial structure of 22.1%. Furthermore, to carry out the re-levering process the tax rate used was assumed to be equal to the weighted average tax rate prevailing from Novo Nordisk business operations, thereby weighing the average tax rate of each geographic segment by the weight of income tax contribution arising from each region over the firm-wide income tax for FY2023. In Exhibit 4.12 the income tax contribution for each region of business operation is reported, moreover the result of the calculation of the average tax rate for each nation constituting the regional segment is reported. The average Tax rate for EMEA region was derived considering the corporate tax rate as of 2023 for each European, African and Middle Eastern country not characterized by extreme default risk. North America region includes Canada, Mexico and Caribbean and Central American countries not characterized by extreme default risk. Rest of the world accounts for all the countries not pertaining to the other regions, such as Asian countries, Oceania countries and South American countries not characterized by extreme default risk. The final result of the weighted average tax rate for Novo Nordisk's business operation was equal to 22.3%.

Exhibit 4.12 *– Weighted Average Tax Rate for Novo Nordisk business operations*

Region	Income tax contribution	Weight	Tax Rate	Weighted Tax Rate
Denmark	12.2	80%	22%	17.5%
EMEA	1	7%	21%	1.4%
China	0.6	4%	25%	1.0%
Rest of the World	0.4	3%	23%	0.6%
USA	1	7%	26%	1.7%
North America excl. USA	0.1	1%	23%	0.1%
Firm-Wide Operations	**15.3**	**1**		**22.3%**

Source: Novo Nordisk Annual Report, Damodaran Tax Rates and Personal Financial Model

By applying the Hamada formula, (formula 4.4), plugging in the industry median unlevered beta, the industry average target leverage and the weighted average tax rate for Novo Nordisk's operations, the levered beta for Novo Nordisk using the Bottom-Up approach was equal to 0.62.

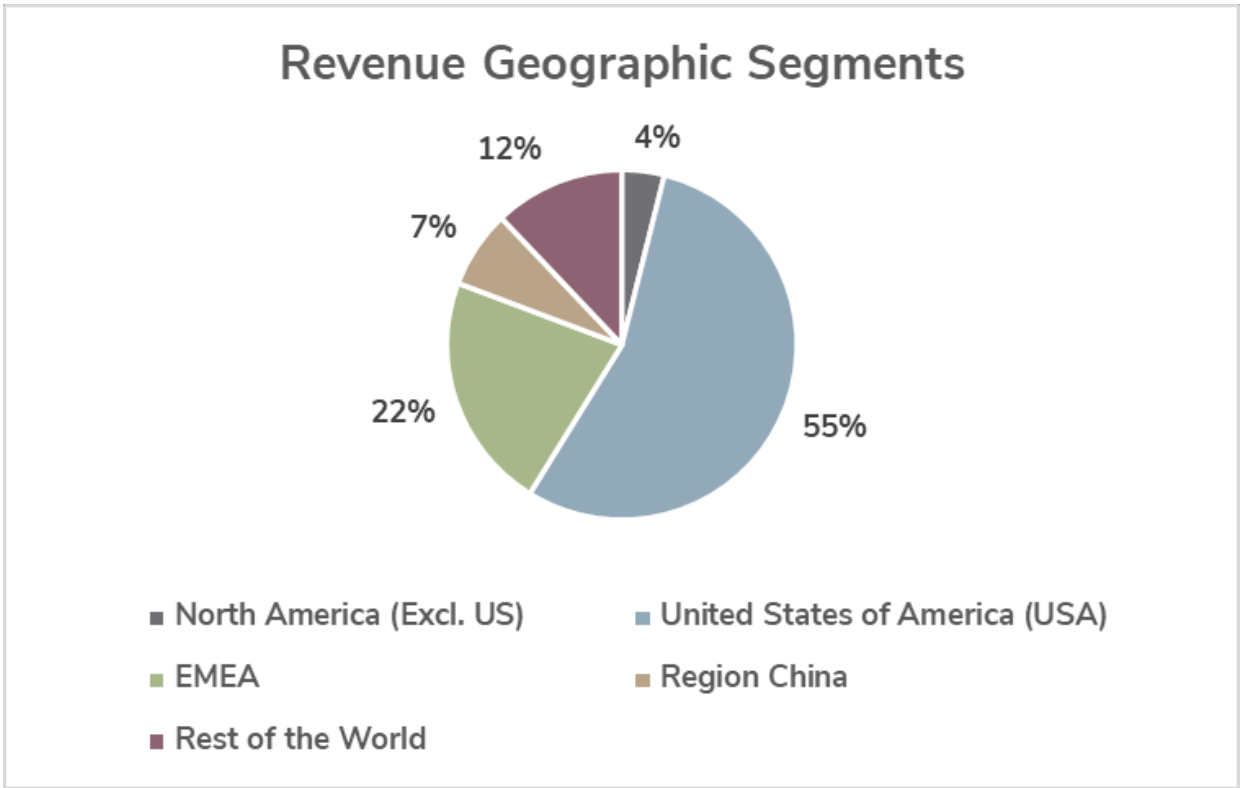
$$\beta_{levered} = \beta_{unlevered} \times \left[1 + \frac{D}{E} \times (1 - t)\right] \quad [4.4]$$

The Equity Risk Premium was assumed to be equal to the ERP of mature equity market, therefore in this case, for consistency principle, assumed to be the U.S. market risk premium, which is equal to 4.6%; the estimate of the ERP for U.S. equity market was based on the data provided by Damodaran as of January 1, 2024[261].

The ERP was then adjusted by accounting for an additional country risk premium in order to reflect the exposure of Novo Nordisk's business operations to different country risks. The CRP used was based on the weighted average CRP related to each geographical segment in which the company generates revenues, weighted by the contribution of each country in generating firm-wide total sales. As depicted in Exhibit 4.13, as of FY2023 the geographic breakdown of revenues reported a 55% of revenues arising from United States, 22% from EMEA, 7% from China, 4% from North America excluding the U.S., and 12% from the rest of the world.

[261] For more information, please refer to Annex C.

Exhibit 4.13 *– Geographic Segments of firm-wide revenues of Novo Nordisk*



Source: Novo Nordisk 2023 Annual Report

For each geographical region the CRP was derived from Damodaran tables as of January 1, 2024. Specifically, for EMEA, North America, and Rest of the World regions, the CRP was derived by calculating the average CRP for each underlying countries, excluding from the computation countries exposed to CRP higher than 20% or characterized by intense geopolitical instability[262]. As a result, the weighted average CRP for Novo Nordisk international operations is equal to 2.01% as depicted in Exhibit 4.14.

[262] The countries excluded are Lebanon, Ukraine, Venezuela, Zambia, Belarus, Russia, Iran, Algeria, Gambia, Guinea, Haiti, North Korea, Sierra Leone, Sudan, Syria, Somalia, Yemen, Zimbabwe, Liberia, Libya, Malawi.

Exhibit 4.14 *– Weighted Average CRP for Novo Nordisk international business operations*

Nation to account CRP	CRP (%)	Weight (%)	Weighted CRP
United States	0.00%	55%	0.0%
EMEA	4.13%	22%	0.9%
Region China	1.03%	7%	0.1%
Rest of the World	6.39%	12%	0.8%
North America (Excl. US)	6.57%	4%	0.3%
Total Firm's Operation			**2.01%**

Source: Novo Nordisk Annual Report, Damodaran ERP tables and Personal Financial Model

The ERP was then adjusted by accounting for an additional country risk premium in order to reflect The CRP thus obtained was added on top of the product of Beta and ERP for mature equity market. Finally, the Size premium was assumed to be negligible since Novo Nordisk's Market Cap falls beyond the scope of Size effects; in parallel, it was assumed a negligible company specific premium for Novo Nordisk. Therefore, by applying the expanded CAPM the firm-wide cost of equity for Novo Nordisk was equal to 9.4%, as depicted in Exhibit 4.15.

Exhibit 4.15 *– Cost of Equity calculation for Novo Nordisk*

Assumptions			
Valuation Date			31/12/2023
Cost of Equity			
Risk Free Rate	Rf	=	4.6%
Unlevered Beta	Bu	=	0.53
Gearing	D/E	=	22.1%
Relevered Beta	BL	=	0.62
Equity Risk Premium	ERP	=	4.6%
Size Premium	SP	=	0.0%
Country Risk Premium	CRP	=	2.0%
Company-Specific Premium (Alpha)	A	=	0.0%
Cost of Equity	**Ke**	=	**9.4%**

Source: Personal Financial Model

The Cost of Equity hereby obtained is consistently higher with respect to the WACC of Novo Nordisk, which was equal to 7.3%. The WACC was obtained by applying the weight of equity, derived from the target industry average leverage ratio (D/E), to the cost of equity, and the relative weight of debt to the after-taxes cost of debt. The pre-tax cost of debt was implied by applying a synthetic credit spread based on the Interest Coverage Ratio score of Novo Nordisk, to the spot

rate of 10 Year U.S. Treasury Bond. The credit spread is derived from Damodaran tables, and it is depicted in Exhibit 4.16. As of the Valuation Date, the EBIT[263] of Novo Nordisk stands at $ 15.21 billion, while the interest expenses amount to $ 80.4 million, therefore the interest coverage ratio for FY2023 was equal to 189.25x, leading to a credit rating of AAA based on the benchmark for large manufacturing firms. By applying the credit spread related to AAA firms, which is equal to 0.69%, to the risk-free rate, equal to 4.58%, the estimated pre-tax cost of debt was equal to 5.27%.

Exhibit 4.16 *– Synthetic Credit Spread for large manufacturing firms*

For large manufacturing firms

If interest coverage ratio is			
>	*≤ to*	*Rating is*	*Spread is*
-100000	0.199999	D2/D	20.00%
0.2	0.649999	C2/C	17.50%
0.65	0.799999	Ca2/CC	15.78%
0.8	1.249999	Caa/CCC	11.57%
1.25	1.499999	B3/B-	7.37%
1.5	1.749999	B2/B	5.26%
1.75	1.999999	B1/B+	4.55%
2	2.2499999	Ba2/BB	3.13%
2.25	2.49999	Ba1/BB+	2.42%
2.5	2.999999	Baa2/BBB	2.00%
3	4.249999	A3/A-	1.62%
4.25	5.499999	A2/A	1.42%
5.5	6.499999	A1/A+	1.23%
6.5	8.499999	Aa2/AA	0.85%
8.50	100000	Aaa/AAA	0.69%

Source: Damodaran

Finally, by applying the benefit of debt financing to the cost of debt, accounting for the interest tax shields, using as a plug-in input the weighted average tax rate for Novo Nordisk international operations, the after-tax cost of debt was equal to 4.1%. In the end the WACC for Novo Nordisk as of 31 December 2023 was equal to 7.1%, as depicted by Exhibit 4.17[264].

[263] Please refer to Annex F for Novo Nordisk Historical Financials.
[264] For more information concerning the WACC estimation and Beta estimation please refer to Annex D and Annex E respectively.

Exhibit 4.17 *– WACC calculation for Novo Nordisk*

Cost of Equity			
Risk Free Rate	Rf	=	4.6%
Unlevered Beta	Bu	=	0.53
Gearing	D/E	=	22.1%
Relevered Beta	BL	=	0.62
Equity Risk Premium	ERP	=	4.6%
Size Premium	SP	=	0.0%
Country Risk Premium	CRP	=	2.0%
Company-Specific Premium (Alpha)	A	=	0.0%
Cost of Equity	**Ke**	=	**9.4%**
Cost of Debt			
Cost of Debt before Tax	Kd(pt)	=	5.3%
Effective Tax Rate	t	=	22.3%
Cost of Debt after Tax	**Kd**	=	**4.1%**
Financial Structure			
Debt-to-Total Capital	**Wd**	=	**44.1%**
Equity-to-Total Capital	**We**	=	**55.9%**
Weighted Average Cost of Capital (WACC)			**7.1%**

Source: Personal Financial Model

4.2.3 Relief from royalty: TAB factor

A further step required to carry out the Relief from Royalty Method is the estimation of Tax Amortization Benefits, arising from the ownership of the U.S. patent along its RUL. In this case, the patent expiration of Ozempic in the United States is expected to be on January 1, 2032. Therefore, the timeframe upon which Legal Life is computed turns out to be from the Valuation Date until December 31, 2031, which is therefore equal to 8 fiscal years. As declared before, in performing the valuation of the U.S. patent of Ozempic, it is reasonable to assume the Legal Life equal to the RUL of the patent. As a result, future Tax Amortization Benefit will be captured in the financial model for the 8 remaining years of the Legal Life. In order to compute the Tax Amortization Benefit, it is required to have available the present value of future economic benefits arising from the ownership of the patent, thus the fair value; however, at the same time, tax amortization benefits are required to estimate the fair value of the patent. In order to avoid this circular reference issue, the TAB factor was computed, and this will be multiplied by the present

value of future cash flows attributable to the patent to determine the Tax Amortization Benefits. In order to compute the TAB factor formula 4.5 was utilized:

$$TAB = \frac{RUL}{RUL - \left((PV[r;RUL;-1] * (1+r)^{0.5}) * t\right)} \quad [4.5]$$

In which:

RUL = Assumed to be equal to the legal life of the patent, thus equal to 8 years;

r = Discount Rate assumed to be equal to the firm-wide levered cost of equity, equal to 9.4%;

t = Tax rate assumed to be equal to the corporate tax rate in the United States as of FY2023, equal to 25.8%.

In this case, the formula implies the assumption of mid-year discount convention, which is reasonable as cash flows can be expected to be distributed evenly during each forecasted year. The results of the calculation of the TAB factor are reported in Exhibit 4.18. As depicted below, the TAB factor was therefore equal to 1.22.

Exhibit 4.18 *– TAB calculation for the U.S. Patent*

Semaglutide (Ozempic) US Patent Valuation
TAB Factor
Valution Date: 31/12/2023

US Semaglutide Patent TAB Factor

RUL	8
Discount Rate	9.4%
PV(DR,RUL,-1)	5.45
PV(DR,RUL,-1)*(1+DR)^0.5	5.70
Tax Rate	25.8%
TAB Factor	1.22

Source: Personal Financial Model

4.2.4 Relief from royalty: Selected Royalty Rate

The final input for the Relief from Royalty method is the estimation of an appropriate royalty rate, upon which the future royalty savings after tax are determined. In order to determine the royalty

rate to be used, a panel of comparable licensing agreements was identified. The licensing agreements were sourced from ktMine database, and the comparability criterion was set based on the similarity of the patent object of licensing and based on a net sales royalty base. In this case, a screening of hundreds of agreements was required, in order to determine a panel of licensing agreements related to patents based on GLP-1 applications and treatments for diabetes. For each licensing agreement selected the corresponding royalty rate on net sales was determined. The results of the screening of comparable royalty agreements are reported in Annex G. The research, conducted based on the above-mentioned characteristics, allowed the identification of nine contractual agreements, for which some descriptive summaries are provided:

i. Licensing agreement between Alteon Inc (Licensor) and Genentech Inc (Licensee), dated 1 December 1997, which grants the right to use and sell treatments for diabetes and complications of diabetes, with a royalty rate on net sales ranging from 10.0% to 15.0%
ii. Licensing agreement between Medical Foods Inc. (Licensor) and Biomune Systems (Licensee), dated 25 September 1998, which grants the usage of patents and trade secrets related to the product NiteBite Timed-release Glucose Bar, with a royalty rate on net sales equal to 12.0%
iii. Licensing agreement between Alkermes (Licensor) and Amylin Pharmaceutical (Licensee), dated 15 May 2000, which grants the right to use and sell GLP-1 agonists products, with a royalty rate on net sales ranging from 3.5% to 25.0%
iv. Licensing agreement between Metabasis Therapeutics (Licensor) and Sankyo Co. LTD (Licensee), dated 21 October 2002, which grants the right to use and sell Next Generation Compounds in the field of Diabetes care, with a royalty rate on net sales equal to 10.0%
v. Licensing agreement between Restoragen Inc (Licensor) and Amylin Pharmaceutical (Licensee), dated 24 December 2002, which grants the right to use all the patents related to products based on GLP-1, with a royalty rate on net sales equal to 6.0%.
vi. Licensing agreement between Alkermes (Licensor) and Amylin Pharmaceutical (Licensee), dated 24 October 2005, which amends the previous licensing agreements, thereby licensing the patent for long-acting formulation of AC2993, with a royalty rate on net sales ranging from 5.5% to 8.0%
vii. Licensing agreement between Depomed Inc (Licensor) and Santarus Inc (Licensee), dated 22 September 2011, which grants the right to produce and sell Glumetza employed in treating type 2 Diabetes, with a royalty rate on net sales ranging from 26.5% to 70.0%

viii. Licensing agreement and Joint venture between I-Mab Biopharma (Licensor) and CSPC Baike (Licensee), dated 10 December 2018, which grants the right to use patented technology related to long-acting recombinant GLP-1 medication, with a royalty rate on net sales ranging from 5.0% to 10.0%

ix. Licensing agreement between Pinata Holdings (Licensor) and Trustfeed Corp (Licensee), dated 29 June 2024, which grants the right to exploit patents and know-how to produce and supply oral GLP-1 capsule, with a royalty rate on net sales ranging equal to 10.0%

The panel of licensing agreements allowed the identification of, minimum, first quartile, median, average, third quartile, and maximum royalty rates applied on Net Sales, ranging from 3.5% to 70.0%. Based on the high variability of the royalty rates thus selected, the median royalty rate, equal to 10.0%, was selected as input for the Relief from Royalty Method. Though such a royalty rate may seem a high value, this is justified by the highly innovative nature of the contents of the agreements examined, as they concern GPL-1 and treatments for diabetes.

4.2.5 Relief from royalty application

Based on the assumptions and inputs determined above, the Relief from Royalty method was applied in order to estimate the fair value of the U.S. patent, thereby calculating as first step the Pre-tax royalty savings along the RUL (from FY2024 to FY2031) of the Ozempic patent. By multiplying the royalty rate determined from the research of comparable licensing agreements, equal to 10.0% to the projected revenues attributable to the Patent, it was possible to obtain the Pre-Tax Royalty Savings. From the projected royalty savings, tax expenses were deducted, assuming the as the tax rate the U.S. corporate tax rate, since the intellectual property asset generates revenues in the United States: taxes are deducted since royalty payments would generate a tax shield, which in this case is not generated as the asset is not being licensed to Novo Nordisk. The projected after-tax royalty savings were discounted using the levered cost of equity thereby obtaining cumulative discounted after-tax royalty savings equal to $ 9.15 billion. Finally, the TAB factor, equal to 1.22, was applied to the cumulative present value of after-tax royalty savings in order to account also for TAB arising from patent ownership. Based on the Relief from royalty method the fair value of Ozempic U.S. patent was estimated to be equal to $ 11.2 billion. A sensitivity analysis to the fair value of the U.S. patent was carried out, by varying the royalty rate up and down by +/- 1.5% and varying the discount rate up and down by +/- 1.0% capturing a range

of fair value between $ 9.20 billion and $ 13.34 billion. The results are shown in Exhibit 4.19[265].

Exhibit 4.19 *– Assumptions used and results from the application of the Relief from Royalty method (millions of USD)*

Selected Royalty Rate	10.00%
Remaining Useful Life (RUL)	8.00
Discount Factor	9.4%
Tax Rate	25.8%
Cumulative Present Value of After-Tax Royalty Savings	**9,147.0**
TAB Factor	1.22
Fair Market Value - US Patent	**11,204.5**
Fair Market Value - US Patent (rounded)	**11,204**

Sensitivity Analysis:

	Royalty Rate				
	7.0%	8.5%	**10.0%**	11.5%	13.0%
7.4%	8,413	10,216	12,019	13,822	15,624
8.4%	8,120	9,860	11,600	**13,340**	15,080
9.4%	7,843	9,524	**11,204**	12,885	14,566
10.4%	7,581	**9,206**	10,830	12,455	14,079
11.4%	7,333	8,904	10,475	12,047	13,618

Discount rate

Source: Personal Financial Model

4.2.6 Rule of thumb – 25%: projection of operating profit

The rule of thumb – 25% method was applied as a sanity check for the fair value estimated through the Relief from Royalty Method. In this case, the rule of thumb was applied by taking the perspective of a Licensor, thus assuming that Novo Nordisk would license the Ozempic Patent in an open market arm's length transaction. In light of this, a common royalty rate applied to licensing agreement is 25.0% having as a royalty base the operating profit. Though the rule of thumb can be considered as an oversimplifying approach, Razgaitis (1999) and Smith & Parr (2005), have stated the prominence of the method in current licensing transactions.

In this case, to perform the rule of thumb method, projections of operating profit (EBIT) attributable to the U.S. patent along its remaining useful life are required. In order to estimate the EBIT attributable to the U.S. patent, an analysis of the historical revenue contribution to overall

[265] For more information concerning the Relief from Royalty Method Application please, refer to Annex H.

sales by Ozempic sales in the United States was performed. Novo Nordisk is characterized by main business segments: Diabetes & Obesity Care and Rare disease. Obesity and Diabetes Care represents the main business line of Novo Nordisk with total revenues equal to $ 31.9 billion as of Fiscal Year 2023. From the annual reports of Novo Nordisk, the historical EBIT for the Obesity and Diabetes Care was calculated for FY2021, FY2022 and FY2023. As depicted in Exhibit 4.20, the historical contribution to Diabetes and Obesity Care overall revenues of the U.S. sales of Ozempic was calculated, thus finding a weight of revenues of 19.1%, 24.8% and 29.3% for FY2021, FY2022 and FY2023 respectively.

Exhibit 4.20 *– Historical EBIT margin for the Diabetes and Obesity Care business segment, and relative calculation of the weight of U.S. Ozempic sales on the overall revenues of the business segment.*

Ozempic (Semaglutide)

Historical Profit Margins in the U.S. market

Million of Dollars

	FY2021	FY2022	FY2023
Revenues from Diabtes and Obesity Care	18,599	22,473	31,898
COGS	(2,962)	(3,311)	(4,521)
SG&A expenses	(5,705)	(6,659)	(8,440)
R&D expenses	(2,386)	(2,896)	(4,163)
Other operating Income / (Expense)	30	128	(1)
D&A	(749)	(819)	(1,215)
EBIT Diabetes and Obesity Care	**6,828**	**8,916**	**13,559**
margin (%)	**36.7%**	**39.7%**	**42.5%**
Revenues Ozempic U.S.	**3,544**	**5,568**	**9,344**
Contribution to Diabetes and Obesity Care	**19.1%**	**24.8%**	**29.3%**

Source: Personal elaboration based on Novo Nordisk Annual Reports.

The weight of revenues of U.S. Ozempic sales thus calculated was used to derive the pro-rata operating expenses related to the Ozempic business operations. Therefore, the operating expenses related to U.S. Ozempic business operations are assumed to have an equal weight of the revenue's contribution of U.S. Ozempic sales, with respect to the overall operating expenses from Diabetes and Obesity Care. As a result, the weight of revenues of Ozempic thus derived, equal to 19.1%, 24.8% and 29.3% for FY2021, FY2022 and FY2023 respectively, was multiplied by each operating expenses line related to Diabetes and Obesity Care business segment. Therefore, the operating margins of Ozempic are assumed to be close akin to the operating margins of the business segment; this assumption can be reasonable since the global revenues of Ozempic contribute to 44.5% of the total revenues arising from Diabetes and Obesity Care. The pro-rata

EBIT margin for U.S. Ozempic's business operation is reported in Exhibit 4.21. As shown, EBIT for Ozempic in the United States was equal to $ 3.97 billion, with an EBIT margin of 42.5%, thus equal to the Diabetes and Obesity Care EBIT margin. In FY2023, the Pro-Rata COGS amounted to $ 1.32 billion, 14.2% of U.S. Ozempic sales, Pro-Rata SG&A expenses amounted to $ 2.47 billion, 26.5% of U.S. Ozempic sales, Pro-Rata R&D expenses amounted to $ 1.22 billion, 13.1% of U.S. Ozempic sales, Pro-Rata Other Operating Expenses amounted to $ 300,000, and finally D&A amounted to $ 0.35 billion, equal to 3.8% of U.S. Ozempic sales.

Exhibit 4.21 *– Historical EBIT margin for the Diabetes and Obesity Care business segment, and relative calculation of the weight of U.S. Ozempic sales on the overall revenues of the business segment. (million of USD).*

Ozempic Pro-Rata Derivation of Historical EBIT

	FY2021	FY2022	FY2023
Revenues Ozempic U.S.	3,544	5,568	9,344
Pro-Rata COGS	(564)	(820)	(1,324)
% of revenues	15.9%	14.7%	14.2%
Pro-Rata SG&A expenses	(1,087)	(1,650)	(2,472)
% of revenues	30.7%	29.6%	26.5%
Pro-Rata R&D Expenses	(455)	(717)	(1,220)
% of revenues	12.8%	12.9%	13.1%
Pro-Rata Other Operating Income / (Expense)	6	32	(0)
% of revenues	0.2%	0.6%	0.0%
Pro-Rata D&A	(143)	(203)	(356)
% of revenues	4.0%	3.6%	3.8%
EBIT Ozempic U.S. Pro-rata	**1,302**	**2,209**	**3,972**
margin (%)	**36.7%**	**39.7%**	**42.5%**

Source: Personal Financial Model.

Starting from the financial estimates of EBIT as of FY2021, FY2022, and FY2023 for Ozempic operations in the United States, from the latest available year EBIT was projected until the last year of the RUL of the U.S. patent, thus until FY2031. The projection of the revenue stream was already estimated when performing the Relief from Royalty Method, as described in section 4.2.1. The operating cost lines were projected based on their average incidence on revenues relative to the historical years FY2021, FY2022 and FY2023. Therefore, the average incidence of COGS on revenues for the 3 previous fiscal years was equal to 14.9%, for SG&A was equal to 28.9%, for R&D expenses was 12.9%, for Other Operating Expenses were equal to 0.2%[266], and finally for D&A was equal to 3.8%. As a result of the assumptions illustrated above, the EBIT as of the last

[266] Other operating income was assumed to be negligible to the analysis.

year of the RUL was equal to $ 9.45 billion, with an EBIT margin of 39.1%.[267] The projections of EBIT attributable to the U.S. patent are reported in Exhibit 4.22.

Exhibit 4.22 *– Projections of EBIT attributable to the U.S. patent related to Ozempic (millions of USD).*

		FY2023 Historical	FY2024 Projected	FY2025 Projected	FY2026 Projected	FY2027 Projected	FY2028 Projected	FY2029 Projected	FY2030 Projected	FY2031 Projected
Revenues		9,344	14,910	20,956	25,472	21,847	22,403	22,973	23,557	24,156
growth (%)			59.6%	40.6%	21.5%	-14.2%	2.5%	2.5%	2.5%	2.5%
Cost of Goods Sold	14.9%	(1,324)	(2,228)	(3,132)	(3,806)	(3,265)	(3,348)	(3,433)	(3,520)	(3,610)
Gross Margin		8,020	12,682	17,825	21,666	18,583	19,055	19,540	20,037	20,546
% on Revenues		85.8%	85.1%	85.1%	85.1%	85.1%	85.1%	85.1%	85.1%	85.1%
SG&A expenses	28.9%	(2,472)	(4,312)	(6,061)	(7,367)	(6,318)	(6,479)	(6,644)	(6,813)	(6,986)
R&D expenses	12.9%	(1,220)	(1,927)	(2,708)	(3,292)	(2,823)	(2,895)	(2,969)	(3,044)	(3,122)
Other Operating Income / (Expense)	0.2%	(0)	(36)	(51)	(62)	(53)	(55)	(56)	(57)	(59)
EBITDA		4,328	6,407	9,005	10,946	9,388	9,627	9,871	10,122	10,380
% on Revenues		46.3%	43.0%	43.0%	43.0%	43.0%	43.0%	43.0%	43.0%	43.0%
Depreciation and Amortization	3.8%	(356)	(571)	(802)	(975)	(836)	(857)	(879)	(901)	(924)
EBIT		**3,972**	**5,836**	**8,203**	**9,971**	**8,552**	**8,769**	**8,992**	**9,221**	**9,455**
% on Revenues		**42.5%**	**39.1%**	**39.1%**	**39.1%**	**39.1%**	**39.1%**	**39.1%**	**39.1%**	**39.1%**

Source: Personal Financial Model.

4.2.7 Application of the Rule of Thumb – 25%

The Rule of Thumb – 25% was used as a control method, in order to validate the findings obtained through the Relief from Royalty Method. By taking the perspective of the Licensor, the value estimated for the U.S. patent through this method will be equal to the present value of after-tax royalty payments, benefiting the Licensor. For this purpose, the profit split method using the 25% rule of thumb is based on the calculation of the projected implied royalty rate for each year of the RUL. The implied royalty rate is derived by taking the product between the 25%, which is the portion of profits allocated to the Licensor in a common licensing agreement, and the Operating Profit Margin (EBIT margin) for each year of the RUL. Furthermore, by computing the product between the implied royalty rate thus obtained and the revenues attributable to the U.S. patent it was possible to estimate the projection of future royalty payments that the Licensor would benefit. The royalty payments are reduced by tax expenses anchored to the American corporate tax rate, in order to account the effect of royalty payments to the taxable income, thereby increasing it: therefore, the projected after-tax royalty payments are derived. The cumulative after-tax royalty payments were then discounted by the levered cost of equity, equal to 9.4%, using the mid-year

[267] The EBIT margin is constant over the RUL of the U.S. patent, as a result of constant incidence of operating costs on the revenues.

discount convention period, as in the case of the Relief from Royalty method. The cumulative present value of after-tax royalty payments was deemed to be equal to $ 8.95 billion. Finally, the TAB factor, equal to 1.22, was applied to the cumulative present value of after-tax royalty payments, thus obtaining a fair market value for the U.S. Patent related to Ozempic equal to $ 10.96 billion. A sensitivity analysis was performed on the fair value thus obtained, varying the profit split ratio based on the rule of thumb by +/- 3.0% and the discount rate by +/- 1.0%. The profit-split ratio embodied a higher sensitivity variation due to empirical findings based on which the profit-split ratio in licensing agreements can be found on average equal to 26.7% in 15 different industries[268]. The results of the application of the Rule of thumb using 25% profit split ratio, and the sensitivity analysis are reported in Exhibit 4.23[269].

Exhibit 4.23 *– Assumptions and Fair value sensitivity obtained by the application of the Rule of Thumb-25% profit split.*

Rule of Thumb - 25% Profit Split	25.00%
Remaining Useful Life (RUL)	8.00
Discount Factor	9.4%
Tax Rate	25.8%
Cumulative Present Value of After-Tax Royalty Payments	**8,951.2**
TAB Factor	1.22
Fair Market Value - US Patent	**10,964.6**
Fair Market Value - US Patent (rounded)	**10,965**

Sensitivity Analysis:

		Profit Split ratio				
		19.0%	22.0%	**25.0%**	28.0%	31.0%
Discount rate	7.4%	8,939	10,350	11,762	13,173	14,584
	8.4%	8,627	9,990	11,352	**12,714**	14,076
	9.4%	8,333	9,649	**10,965**	12,280	13,596
	10.4%	8,055	**9,326**	10,598	11,870	13,142
	11.4%	7,791	9,021	10,251	11,481	12,712

Source: Personal Financial Model.

From the sensitivity of the Fair market value of the patent obtained through the application of the Rule of Thumb, equal to a range of $ 9.33 billion and $ 12.71 billion, it can be inferred that the method supports the findings of the Relief from Royalty Method.

[268] Smith G. Parr L., (2005), Valuation of Intellectual Property and Intangible Assets, 278-282.
[269] For more information concerning the application of the Profit Split method with the rule of thumb, please refer to Annex I.

4.3 Summary: Valuation of the U.S. Patent related to Ozempic

The application of the Relief from Royalty Method to value the U.S. patent related to Ozempic estimated the fair market value of the U.S. patent in a range between $ 9.20 billion and $ 13.34 billion. The value obtained from the Relief from the Royalty Method is fully supported by the fair value range estimated by the Rule of Thumb using the 25% profit split, equal to $ 9.33 billion and $ 12.71 billion. As a result, it is demonstrated that the Relief from Royalty method thus applied can be considered reliable: consequently, it can be inferred that the Fair Market Value range of the U.S. Patent related to Ozempic is between $ 9.20 billion, equal to the lower bound of the sensitivity analysis from the Relief from Royalty Method, and $ 13.34 billion, equal to the upper bound of the sensitivity from the Relief from Royalty method. Therefore, as reported in the football field in Exhibit 4.24, it is reasonable to anchor the Fair Market Value to the value obtained initially from the application of the primary method, thus equal to $ 11.204 billion. As of December 31, 2023, based on the application of the Relief from Royalty method, and as confirmed by the Profit Split method using the 25% Rule of Thumb, the Fair Market Value of the U.S. Patent related to Ozempic is estimated to be equal to $ 11,204 million.

Exhibit 4.24 *– Football field valuation summary for the U.S. patent related to Ozempic.*

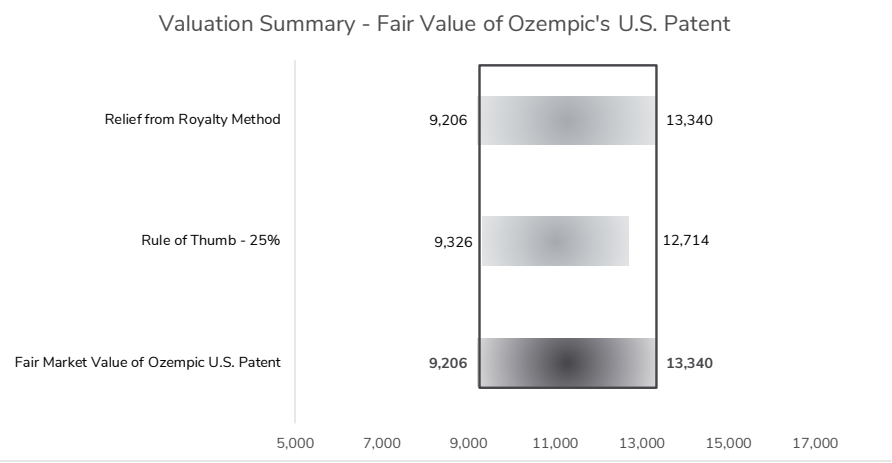
Ozempic (Semaglutide)

Estimate of the fair market value of the U.S. Patent as of December 31, 2023

Football Field

Million of Dollars

	Low	High
Relief from Royalty Method Fair Value of the U.S. Patent	9,206	13,340
Rule of Thumb - 25% Fair Value of the U.S. Patent	9,326	12,714
Fair Value of Ozempic U.S. Patent	9,206	13,340
Estimated Fair Market Value	**11,204**	



Source: Personal Financial Model.

Conclusion

During the course of this analysis, it has been highlighted the strategic role of Intellectual Property Rights for firms in the Life Sciences Industry. The various kinds of Intellectual Property Rights, spanning from patents and trademarks to copyrights and trade secrets, protect inventions of Biopharmaceutical companies, granting, at the same time, exclusive rights upon which the owner can benefit from future economic benefits. Intellectual Property Rights, as discussed in Chapter 2, play a crucial role in driving innovation across the Life Sciences Industry. Indeed, the capital-intensive on-going R&D processes are the primer for the value chain of Biopharma companies, as new chemical compounds are continuously analyzed in order to find effective applications for treating human and animal medical conditions. Due to the significant investments that are required by the multiple R&D pipelines, Biopharma companies must secure and guarantee a sufficient return on these investments. In this regard, Intellectual Property Rights are able to protect Biopharmaceutical inventions from reverse engineering, carried out by generic competitors, avoiding their investments in the lengthy R&D processes to be vanished. Moreover, Intellectual Property Rights play a pivotal role in securing a sufficient return on R&D capital expenditures: by virtue of the legal rights stemming from them, Biopharmaceutical companies can charge premium prices, as in the case of trademarks and patents, thereby securing positive IRR on their R&D investments. Intellectual Property Rights in the Life Sciences sector represent a valuable asset from a transactional perspective, several early-stage Biotechnological companies are able to benefit from economic benefits by licensing the patents or trade secrets associated with their inventions to bigger pharmaceutical companies. Finally, Intellectual Property Rights represents a valuable asset to attract fundings, since Private Equity Funds and Venture Capital Funds would not be incentivized to invest in potential medical treatment that is not protected by IP rights.

The Ozempic case study brings an example of how a big pharmaceutical company can exploit IP rights in order to intensify the magnitude of cash flows arising from a blockbuster drug. Novo Nordisk thanks to the U.S. Patent protection, is able to charge a premium price in the United States and at the same time protect this blockbuster drug from generic competition, which could depress the staggering profit margins achieved in recent years. Given the prominence of GLP-1 drugs in our society, it was deemed to be meaningful to appraise the fair market value of an Intellectual Property Rights in the Life Sciences Sector, such as the U.S. Patent related to Ozempic, which in turns can give an example of the magnitude of added value that IP rights play for this industry. This Valuation can give a rough estimate of a Fair Value of Intellectual Property Assets, that since

they are in most cases internally generated, cannot be reported in the balance sheet.

The present analysis has led to the identification of a reliable methodology for evaluating a patent associated with a blockbuster drug in the life sciences sector in the presence of limited public data. The methodology indicated by this research is the Relief from Royalty Method, which, by combining a market perspective with the income approach, is capable of authentically representing the value of the patent, considering the frequency of licensing agreements involving pharmaceutical patents. Additionally, the selected methodology provides sufficient flexibility to the evaluator, demonstrating applicability in the presence of limited public information. Furthermore, the reliability of the results obtained from the Relief from Royalty Method was successfully verified through the application of the Rule of Thumb method based on a 25% profit split, a methodology historically used in the legal field for determining royalty rates in favor of the licensor in licensing agreements. In fact, the central value derived from the application of the Relief from Royalty Method and its sensitivity analysis is fully supported by the valuation range derived from the application of the Rule of Thumb method based on a 25% profit split.

In obtaining these findings, an extensive review of the state of the art of valuation methods for intellectual property rights was conducted. In this regard, the academic literature does not present a unanimous orientation towards a standard empirical methodology for the valuation of intangible assets, and more specifically for the valuation of intellectual property rights, as exemplified in this study with patents. The literature underscores the centrality of the necessary information, the requirement for its availability, and the comparability of the reference parameters adopted. Pharmaceutical patents, in this context, exhibit peculiar characteristics associated with highly confidential information and the challenge of accessing such data. Consequently, these factors introduce complexity in the selection of an appropriate valuation method.

The first major topic of discussion in academic literature pertains to the identification of the future economic benefits derived from the ownership and exploitation of intellectual property, as they constitute the primary driver of the intrinsic value of such intangible assets. In this regard, a substantial stream of literature posits that the cost approach is not suitable, as it would negate the existence of future economic benefits, as asserted by Guatri & Bini and Smith & Parr. In line with this stream of literature, the cost approach has not been considered in the empirical valuation exercise presented herein for the American patent of Ozempic. The academic literature acknowledges that, although the market approach can encapsulate the entirety of future economic

benefits deriving from intellectual property exploitation within the market price—being the result of the agreement between buyer and seller in an arm's length transaction—the method faces significant practical limitations due to the scarcity of transactions and the low degree of comparability between the asset under valuation and the one transacted in the market. In the empirical application reported in this study, a lack of asset purchase agreements involving sufficiently comparable patents was identified, thus confirming the infeasibility of applying the market approach. Academic literature, including Guatri & Bini, Hagelin, Smith & Parr, and Reilly & Schweihs, asserts that the income approach authentically represents the value of an intellectual property asset, as it captures the prospective economic benefits arising from its ownership. Regarding patents, Parr & Smith and Reilly & Schweihs highlight the presence of direct methodologies, as in the case of identifying a premium pricing effect stemming from patent ownership. However, in this study, it was demonstrated that the identification of a premium pricing effect directly attributable to the American patent of Ozempic was unfeasible, given the absence of fully comparable generic products in the U.S. market due to the exclusivity restrictions imposed by the patent itself. Nonetheless, these authors also report the existence of indirect methodologies in cases where the direct identification of future economic benefits is impracticable. In this regard, Smith & Parr suggest employing the relief from royalty method as a surrogate measure, which estimates the relief from royalty payments rather than the direct income generated by the patent throughout its remaining useful life. However, Smith & Parr and Hagelin argue that this method may, at times, be inapplicable due to the lack of licensing agreements involving comparable patents, and it is also subject to considerable variability stemming from the selection of royalty rates, which could either overestimate or underestimate the patent's value. In the empirical case analyzed in this study, by screening public data from ktMine, a database referenced in the literature by Reilly & Schweihs, the existence of nine licensing agreements for the use and sale of GLP-1 agonist-based products, similar to Ozempic, was identified. Furthermore, the empirical analysis demonstrated that the applied royalty rate led to a non-skewed valuation using the relief from royalty method, as the valuation ranges were confirmed by the control method employing the rule of thumb with a 25% profit split, as suggested by Smith & Parr and Vulpiani, assessing the robustness of the primary method. Consequently, the validity of the valuation method was substantiated.

Regarding the control valuation method adopted in this empirical study, namely the rule of thumb utilizing the 25% profit split, Smith & Parr empirically demonstrated the existence of a median

royalty rate, as a percentage of the licensee's average operating profit margin, equal to 26.7% across 15 industries, including the pharmaceutical sector, thereby exhibiting consistency with the 25% rule. However, these authors maintain that the 25% rule should be regarded as merely a crude guideline for estimating the magnitude of royalty rates and recommend the use of EBIT as an economic parameter for their estimation. Razgaitis, in this regard, supports the 25% rule by employing gross profit as the economic parameter, justifying the rule qualitatively rather than empirically. Conversely, Stiroh & Rapp reject the 25% rule, citing empirical surveys that establish 10% as the maximum royalty rate on gross profits in licensing agreements. In the empirical case presented in this study, EBIT margin was used as the economic parameter in the rule of thumb with the 25% profit split, contrary to the approaches suggested by Razgaitis and Stiroh & Rapp. However, the valuation ranges derived from this method overlapped with those obtained through the relief from royalty method, reinforcing its consistency. If considering the perspective of Reilly & Schweihs, who regard the relief from royalty method as a robust approach for intellectual property valuation, then the findings obtained using the rule of thumb with the 25% profit split—which align with those derived from the relief from royalty method—validate the applicability of the 25% rule. In this sense, based on the empirical findings, this study supports the view of Smith & Parr and Vulpiani, who argue that the 25% rule can be employed as a control method in intellectual property valuations.

The second major area of academic debate concerns the selection of an appropriate discount rate to discount the future economic benefits derived from IP ownership. Mard, Hitchner, and Hyden, in their empirical study, adopt assumed discount rates based on experience for specific intangible assets. However, this approach was not applied in the valuation of Ozempic's patent, as it fails to account for the asset-specific risks and those associated with the company holding it. Reilly & Schweihs, in their application of the relief from royalty method, report the use of WACC as the discount factor. However, applying WACC to the valuation of Ozempic's patent would result in an overvaluation, considering that the patent entails an inherently higher risk than Novo Nordisk's overall business. Consequently, this approach was not considered in this study. Instead, in the empirical analysis, the levered cost of equity was applied in both the relief from royalty method and the rule of thumb with a 25% profit split, accounting for the patent's higher risk relative to Novo Nordisk's overall business. In this regard, the two valuation methodologies employed in this study align with the perspective of Stegink, Schauten, and Graaff, who argue that the levered cost of equity is a reliable proxy for discount rate estimation in intangible asset valuation. Conversely,

the approach advocated by Smith & Parr, which suggests that the unlevered cost of equity could be considered a proxy for the discount rate of intangible assets, was not adopted in this valuation case. Finally, within the analysed academic literature, no prior empirical study has been identified that explicitly employs the combined use of the relief from royalty method and the rule of thumb with a 25% profit split for the valuation of pharmaceutical patents. Accordingly, this study can be regarded as an empirical contribution to the existing body of literature on intellectual property valuation.

With reference to the specificity of the empirical valuation case, after reviewing the various Intellectual Property valuation methods, the Cost Approach and the Market Approach, to this extent, were considered to be inappropriate. The Cost Approach was deemed to be not appropriate, due to the fact that the method does not account for future economic benefits of the ownership of the patent related to Ozempic. Moreover, the difficulty in estimating the level of economic obsolescence due to the uniqueness of Intellectual Property Assets, coupled with the limited availability of reproduction costs, made this method not feasible. The Market Approach was not considered in this analysis due to the limited availability and low degree of comparability of recent acquisitions involving patents for GLP-1 medications. Finally, the Income Approach was taken into consideration in the form of the Relief from Royalty Method, as primary method, and the 25% Rule of Thumb Method, as a control method: the Income Approach was selected given its capacity to capture future economic benefits arising from the ownership of the Patent, which in this case for a blockbuster drug in full expansion, like Ozempic, appears to be crucial.

During the Valuation process, several assumptions have been made, the first pertaining to the scope of the valuation of the Patent under consideration: since it is an internally generated intangible asset, the patent can be reported in Novo Nordisk's financial statements. For this reason, the simplifying premise of considering the business unit in which U.S. sales of Ozempic are generated as a target of a hypothetical acquisition was required, thus taking the perspective of a Purchase Price Allocation. Moreover, given the limited availability concerning contributory asset charges and their fair values, the Multi Period Excess Earnings Method was deemed to be not feasible. In spite of this, in the computation of the discount rate the WACC-WARA reconciliation was not applied due to limited information concerning return on and return of the contributory assets of the U.S. patent. Therefore, a simplifying assumption was taken, according to which the appropriate discount rate for the Ozempic U.S. Patent was assumed to be equal to the levered cost of equity, consistent with the findings of Stegink, Schauten, and Graaff. Furthermore, this

assumption is consistent with the principle according to which the discount rate of an intangible asset should be higher with the firm-wide WACC, as intangible assets have a higher inherent risk. Finally, another key simplifying assumption was to consider the revenues generated by the sales of Ozempic in the United States, as entirely attributable to the patent exploitation. This assumption can be justified by the fact that Ozempic enjoys a unique application for treating type 2 diabetes and at the same time treating weight loss and cardiovascular complications. Moreover, this assumption can be justified by the fact that Novo Nordisk can charge a premium price, until 2027 due to the impact of U.S. IRA for Medicare treatments, thanks to the monopoly rights stemming from the patent ownership.

In light of the valuation analysis so far carried out, the Fair Value of the U.S. patent for Ozempic is estimated to be approximately equal to $ 11.2 billion, using the Relief from Royalty Method as primary method, and the 25% Rule of Thumb as control method.

The valuation exercise presented so far has been able to identify a reliable valuation method under the presence of limited public information, for patents associated with blockbuster drugs, constituting the crucial product line for big pharma companies, as in the case of Novo Nordisk's Ozempic. The Fair Market Value thus determined can be considered as a reference to appraise the importance of patent rights in enhancing blockbuster drugs profitability, offering a monetary example of the crucial role of intellectual property rights, as in the case of the American patent for Ozempic, for a continuously innovating sector such as the Life Sciences Industry.

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Annex

ANNEX A

Comparable companies of the automation industry
Million of Euro

Curr. (in millions)	EUR
Date Market Capitalisation	31/12/2022
Date Assets/Equity/TBV	31/12/2022

Company	Primary Industry	Country	Ticker	Market Cap
Johnson & Johnson	Pharmaceuticals	United States	NYSE:JNJ	432,152
Roche Holding AG	Pharmaceuticals	Switzerland	SWX:ROG	262,258
Pfizer Inc.	Pharmaceuticals	United States	NYSE:PFE	269,132
Thermo Fisher Scientific Inc.	Life Sciences Tools and Services	United States	NYSE:TMO	203,045
Novo Nordisk A/S	Pharmaceuticals	Denmark	CPSE:NOVO B	284,852
Eli Lilly and Company	Pharmaceuticals	United States	NYSE:LLY	325,262
AbbVie Inc.	Biotechnology	United States	NYSE:ABBV	267,336
Danaher Corporation	Life Sciences Tools and Services	United States	NYSE:DHR	180,792
Novartis AG	Pharmaceuticals	Switzerland	SWX:NOVN	181,945
Merck & Co., Inc.	Pharmaceuticals	United States	NYSE:MRK	263,214
AstraZeneca PLC	Pharmaceuticals	United Kingdom	LSE:AZN	195,975
Bristol-Myers Squibb Company	Pharmaceuticals	United States	NYSE:BMY	149,435
Amgen Inc.	Biotechnology	United States	NasdaqGS:AMGN	131,128
Sanofi	Pharmaceuticals	France	ENXTPA:SAN	112,665
Zoetis Inc.	Pharmaceuticals	United States	NYSE:ZTS	63,911
Merck KGaA	Pharmaceuticals	Germany	XTRA:MRK	78,651
GSK plc	Pharmaceuticals	United Kingdom	LSE:GSK	65,820
Moderna, Inc.	Biotechnology	United States	NasdaqGS:MRNA	64,569
Gilead Sciences, Inc.	Biotechnology	United States	NasdaqGS:GILD	100,753
Regeneron Pharmaceuticals, Inc.	Biotechnology	United States	NasdaqGS:REGN	72,102
BioNTech SE	Biotechnology	Germany	NasdaqGS:BNTX	34,159
Lonza Group AG	Life Sciences Tools and Services	Switzerland	SWX:LONN	34,016
Illumina, Inc.	Life Sciences Tools and Services	United States	NasdaqGS:ILMN	29,761
Vertex Pharmaceuticals Incorporated	Biotechnology	United States	NasdaqGS:VRTX	69,361
IQVIA Holdings Inc.	Life Sciences Tools and Services	United States	NYSE:IQV	35,609
Chugai Pharmaceutical Co., Ltd.	Pharmaceuticals	Japan	TSE:4519	39,312
Bayer Aktiengesellschaft	Pharmaceuticals	Germany	XTRA:BAYN	47,476
Sartorius Stedim Biotech S.A.	Life Sciences Tools and Services	France	ENXTPA:DIM	27,883
Daiichi Sankyo Company, Limited	Pharmaceuticals	Japan	TSE:4568	57,809
Agilent Technologies, Inc.	Life Sciences Tools and Services	United States	NYSE:A	41,458
Sartorius Aktiengesellschaft	Life Sciences Tools and Services	Germany	XTRA:SRT3	24,078
Takeda Pharmaceutical Company Limited	Pharmaceuticals	Japan	TSE:4502	45,347
Mettler-Toledo International Inc.	Life Sciences Tools and Services	United States	NYSE:MTD	30,153
Biogen Inc.	Biotechnology	United States	NasdaqGS:BIIB	37,313
West Pharmaceutical Services, Inc.	Life Sciences Tools and Services	United States	NYSE:WST	16,303
Astellas Pharma Inc.	Pharmaceuticals	Japan	TSE:4503	25,949
Genmab A/S	Biotechnology	Denmark	CPSE:GMAB	25,843
Avantor, Inc.	Life Sciences Tools and Services	United States	NYSE:AVTR	13,305
Revvity, Inc.	Life Sciences Tools and Services	United States	NYSE:RVTY	16,573
ICON Public Limited Company	Life Sciences Tools and Services	Ireland	NasdaqGS:ICLR	14,840
Eurofins Scientific SE	Life Sciences Tools and Services	Luxembourg	ENXTPA:ERF	12,900
Waters Corporation	Life Sciences Tools and Services	United States	NYSE:WAT	19,043
Bio-Rad Laboratories, Inc.	Life Sciences Tools and Services	United States	NYSE:BIO	11,659
UCB SA	Pharmaceuticals	Belgium	ENXTBR:UCB	13,973
Shionogi & Co., Ltd.	Pharmaceuticals	Japan	TSE:4507	13,893
Bio-Techne Corporation	Life Sciences Tools and Services	United States	NasdaqGS:TECH	12,173
Alnylam Pharmaceuticals, Inc.	Biotechnology	United States	NasdaqGS:ALNY	27,358
Otsuka Holdings Co., Ltd.	Pharmaceuticals	Japan	TSE:4578	16,575
Charles River Laboratories International, Inc.	Life Sciences Tools and Services	United States	NYSE:CRL	10,374
argenx SE	Biotechnology	Netherlands	ENXTBR:ARGX	19,269

Source: Personal financial model, the data are sourced from S&P Capital IQ.

The sample is composed by the top 50 companies for market cap as of 2022 according to S&P Capital IQ, operating in the Pharmaceutical, Biotechnology and Life Sciences Tool and Services. In order to derive the multiples shown in the analysis in section 2.2, historical LTM revenues and EBITDA metrics for this companies have been calculated, in order to derive the trailing LTM EV/Revenues and EV/EBITDA shown quarterly, from Q4 2019 – Q4 2022.

ANNEX B

Ozempic (Semaglutide) U.S. Patent

Projected Revenues from U.S. Market

Million of Dollars

			FY2023 Historical	FY2024 Projected	FY2025 Projected	FY2026 Projected	FY2027 Projected	FY2028 Projected	FY2029 Projected	FY2030 Projected	FY2031 Projected
Yearly Treatment Expected Price	(1)	**$0.011**	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011
Yearly Treatment Price under Medicare D	*(2)*	**$0.004**					0.004	0.004	0.004	0.004	0.004
Expected yearly treatments (Total)	(3)		831,927	1,327,428	1,865,765	2,267,817	2,325,489	2,384,626	2,445,268	2,507,452	2,571,217
Growth rate (%)	(4)			59.6%	40.6%	21.5%	2.5%	2.5%	2.5%	2.5%	2.5%
of which Treatments under Medicare D	(5)		216,301	345,131	485,099	589,633	604,627	620,003	635,770	651,937	668,516
of which Treatments excluding Medicare D			615,626	982,297	1,380,666	1,678,185	1,720,862	1,764,623	1,809,498	1,855,514	1,902,700
Revenues from Medicare D			2,429	3,877	5,449	6,623	2,519	2,583	2,648	2,716	2,785
Revenues excluding Medicare D			6,915	11,033	15,508	18,849	19,329	19,820	20,324	20,841	21,371
Revenues from yearly treatments			**9,344**	**14,910**	**20,956**	**25,472**	**21,847**	**22,403**	**22,973**	**23,557**	**24,156**
Growth rate (%)				59.6%	40.6%	21.5%	-14.2%	2.5%	2.5%	2.5%	2.5%

Footnotes

(1) The price of a monthly dose of Ozempic is currently marketed at $ 936.00, this price is assumed to remain constant during the forecast period.

(2) Expected price of yearly treatment of Ozempic for patients under Medicare D, as a result of negotiations by the Inflation Reduction Act, effective from 2027.

(3) 2023 Expected yearly treatments derive from the ratio bewteen sales and average price, for the following years treatments are projected based on a historical CAGR (FY2021-FY2023) for 2024, thereby d until FY2027 stabilizing at a long-term growth rate of 2.5% until 2032, based on the estimated CAGR for 2040 of Diabetes Type 2 patients in the United States.

(4) FY2024 growth rate based on historical CAGR (FY2023-FY2021), decreasing linearly by 19.6% until FY2027, thereby holding the long-term CAGR of expected Diabetes Type 2 patients for 2040.

(5) Assumed to be equal to the portion of medicare enrollees for Diabetic Treatment , equal to 26%. Source: CMS.Gorv

ANNEX C

Country	Africa	Moody's rating	*Rating-based Default Spread*	*Total Equity Risk Premium*	*Country Risk Premium*
Abu Dhabi	Middle East	Aa2	0.54%	5.32%	0.72%
Albania	Eastern Europe & Russia	B1	4.90%	11.18%	6.58%
Andorra (Principality of)	Western Europe	Baa2	2.07%	7.38%	2.78%
Angola	Africa	B3	7.08%	14.11%	9.51%
Argentina	Central and South America	Ca	13.07%	22.15%	17.55%
Armenia	Eastern Europe & Russia	Ba3	3.92%	9.86%	5.26%
Aruba	Caribbean	Baa2	2.07%	7.38%	2.78%
Australia	Australia & New Zealand	Aaa	0.00%	4.60%	0.00%
Austria	Western Europe	Aa1	0.44%	5.18%	0.58%
Azerbaijan	Eastern Europe & Russia	Ba1	2.73%	8.26%	3.66%
Bahamas	Caribbean	B1	4.90%	11.18%	6.58%
Bahrain	Middle East	B2	5.99%	12.64%	8.04%
Bangladesh	Asia	B1	4.90%	11.18%	6.58%
Barbados	Caribbean	B3	7.08%	14.11%	9.51%
Belarus	Eastern Europe & Russia	C	17.50%	28.09%	23.49%
Belgium	Western Europe	Aa3	0.65%	5.48%	0.88%
Belize	Central and South America	Caa2	9.81%	17.77%	13.17%
Benin	Africa	B1	4.90%	11.18%	6.58%
Bermuda	Caribbean	A2	0.92%	5.84%	1.24%
Bolivia	Central and South America	Caa1	8.17%	15.57%	10.97%
Bosnia and Herzegovina	Eastern Europe & Russia	B3	7.08%	14.11%	9.51%
Botswana	Africa	A3	1.31%	6.35%	1.75%
Brazil	Central and South America	Ba2	3.28%	9.00%	4.40%
Bulgaria	Eastern Europe & Russia	Baa1	1.74%	6.94%	2.34%
Burkina Faso	Africa	Caa1	8.17%	15.57%	10.97%
Cambodia	Asia	B2	5.99%	12.64%	8.04%
Cameroon	Africa	Caa1	8.17%	15.57%	10.97%
Canada	North America	Aaa	0.00%	4.60%	0.00%
Cape Verde	Africa	B3	7.08%	14.11%	9.51%
Cayman Islands	Caribbean	Aa3	0.65%	5.48%	0.88%
Chile	Central and South America	A2	0.92%	5.84%	1.24%
China	Asia	A1	0.77%	5.63%	1.03%
Colombia	Central and South America	Baa2	2.07%	7.38%	2.78%
Congo (Democratic Republic of)	Africa	B3	7.08%	14.11%	9.51%
Congo (Republic of)	Africa	Caa2	9.81%	17.77%	13.17%
Cook Islands	Australia & New Zealand	B1	4.90%	11.18%	6.58%
Costa Rica	Central and South America	B1	4.90%	11.18%	6.58%
Côte d'Ivoire	Africa	Ba3	3.92%	9.86%	5.26%
Croatia	Eastern Europe & Russia	Baa2	2.07%	7.38%	2.78%
Cuba	Caribbean	Ca	13.07%	22.15%	17.55%
Curacao	Caribbean	Baa3	2.39%	7.81%	3.21%
Cyprus	Western Europe	Baa2	2.07%	7.38%	2.78%
Czech Republic	Eastern Europe & Russia	Aa3	0.65%	5.48%	0.88%
Denmark	Western Europe	Aaa	0.00%	4.60%	0.00%
Dominican Republic	Caribbean	Ba3	3.92%	9.86%	5.26%
Ecuador	Central and South America	Caa3	10.90%	19.23%	14.63%
Egypt	Africa	Caa1	8.17%	15.57%	10.97%
El Salvador	Central and South America	Caa3	10.90%	19.23%	14.63%
Estonia	Eastern Europe & Russia	A1	0.77%	5.63%	1.03%
Ethiopia	Africa	Caa2	9.81%	17.77%	13.17%
Fiji	Asia	B1	4.90%	11.18%	6.58%
Finland	Western Europe	Aa1	0.44%	5.18%	0.58%
France	Western Europe	Aa2	0.54%	5.32%	0.72%
Gabon	Africa	Caa1	8.17%	15.57%	10.97%
Georgia	Eastern Europe & Russia	Ba2	3.28%	9.00%	4.40%
Germany	Western Europe	Aaa	0.00%	4.60%	0.00%
Ghana	Africa	Caa3	10.90%	19.23%	14.63%
Greece	Western Europe	Ba1	2.73%	8.26%	3.66%
Guatemala	Central and South America	Ba1	2.73%	8.26%	3.66%
Guernsey (States of)	Western Europe	A1	0.77%	5.63%	1.03%
Honduras	Central and South America	B1	4.90%	11.18%	6.58%
Hong Kong	Asia	Aa3	0.65%	5.48%	0.88%
Hungary	Eastern Europe & Russia	Baa2	2.07%	7.38%	2.78%
Iceland	Western Europe	A2	0.92%	5.84%	1.24%
India	Asia	Baa3	2.39%	7.81%	3.21%
Indonesia	Asia	Baa2	2.07%	7.38%	2.78%
Iraq	Middle East	Caa1	8.17%	15.57%	10.97%
Ireland	Western Europe	Aa3	0.65%	5.48%	0.88%
Isle of Man	Western Europe	Aa3	0.65%	5.48%	0.88%
Israel	Middle East	A1	0.77%	5.63%	1.03%
Italy	Western Europe	Baa3	2.39%	7.81%	3.21%
Jamaica	Caribbean	B1	4.90%	11.18%	6.58%
Japan	Asia	A1	0.77%	5.63%	1.03%
Jersey (States of)	Western Europe	Aa3	0.65%	5.48%	0.88%
Jordan	Middle East	B1	4.90%	11.18%	6.58%
Kazakhstan	Eastern Europe & Russia	Baa2	2.07%	7.38%	2.78%
Kenya	Africa	B3	7.08%	14.11%	9.51%
Korea	Asia	Aa2	0.54%	5.32%	0.72%
Kuwait	Middle East	A1	0.77%	5.63%	1.03%
Kyrgyzstan	Eastern Europe & Russia	B3	7.08%	14.11%	9.51%
Laos	Asia	Caa3	10.90%	19.23%	14.63%
Latvia	Eastern Europe & Russia	A3	1.31%	6.35%	1.75%
Lebanon	Middle East	C	17.50%	28.09%	23.49%
Liechtenstein	Western Europe	Aaa	0.00%	4.60%	0.00%
Lithuania	Eastern Europe & Russia	A2	0.92%	5.84%	1.24%
Luxembourg	Western Europe	Aaa	0.00%	4.60%	0.00%
Macao	Asia	Aa3	0.65%	5.48%	0.88%
Macedonia	Eastern Europe & Russia	Ba3	3.92%	9.86%	5.26%
Malaysia	Asia	A3	1.31%	6.35%	1.75%
Maldives	Asia	Caa1	8.17%	15.57%	10.97%
Mali	Africa	Caa2	9.81%	17.77%	13.17%
Malta	Western Europe	A2	0.92%	5.84%	1.24%
Mauritius	Africa	Baa3	2.39%	7.81%	3.21%
Mexico	Central and South America	Baa2	2.07%	7.38%	2.78%
Moldova	Eastern Europe & Russia	B3	7.08%	14.11%	9.51%
Mongolia	Asia	B3	7.08%	14.11%	9.51%
Montenegro	Eastern Europe & Russia	B1	4.90%	11.18%	6.58%
Montserrat	Caribbean	Baa3	2.39%	7.81%	3.21%
Morocco	Africa	Ba1	2.73%	8.26%	3.66%
Mozambique	Africa	Caa2	9.81%	17.77%	13.17%
Namibia	Africa	B1	4.90%	11.18%	6.58%
Netherlands	Western Europe	Aaa	0.00%	4.60%	0.00%
New Zealand	Australia & New Zealand	Aaa	0.00%	4.60%	0.00%
Nicaragua	Central and South America	B3	7.08%	14.11%	9.51%
Niger	Africa	Caa2	9.81%	17.77%	13.17%
Nigeria	Africa	Caa1	8.17%	15.57%	10.97%
Norway	Western Europe	Aaa	0.00%	4.60%	0.00%
Oman	Middle East	Ba1	2.73%	8.26%	3.66%
Pakistan	Asia	Caa3	10.90%	19.23%	14.63%
Panama	Central and South America	Baa2	2.07%	7.38%	2.78%
Papua New Guinea	Asia	B2	5.99%	12.64%	8.04%
Paraguay	Central and South America	Ba1	2.73%	8.26%	3.66%
Peru	Central and South America	Baa1	1.74%	6.94%	2.34%
Philippines	Asia	Baa2	2.07%	7.38%	2.78%
Poland	Eastern Europe & Russia	A2	0.92%	5.84%	1.24%
Portugal	Western Europe	A3	1.31%	6.35%	1.75%
Qatar	Middle East	Aa3	0.65%	5.48%	0.88%
Ras Al Khaimah (Emirate of)	Middle East	A3	1.31%	6.35%	1.75%
Romania	Eastern Europe & Russia	Baa3	2.39%	7.81%	3.21%
Rwanda	Africa	B2	5.99%	12.64%	8.04%
Saudi Arabia	Middle East	A1	0.77%	5.63%	1.03%
Senegal	Africa	Ba3	3.92%	9.86%	5.26%
Serbia	Eastern Europe & Russia	Ba2	3.28%	9.00%	4.40%
Sharjah	Middle East	Ba1	2.73%	8.26%	3.66%
Singapore	Asia	Aaa	0.00%	4.60%	0.00%
Slovakia	Eastern Europe & Russia	A2	0.92%	5.84%	1.24%
Slovenia	Eastern Europe & Russia	A3	1.31%	6.35%	1.75%
Solomon Islands	Asia	Caa1	8.17%	15.57%	10.97%
South Africa	Africa	Ba2	3.28%	9.00%	4.40%
Spain	Western Europe	Baa1	1.74%	6.94%	2.34%
Sri Lanka	Asia	Ca	13.07%	22.15%	17.55%
St. Maarten	Caribbean	Ba2	3.28%	9.00%	4.40%
St. Vincent & the Grenadines	Caribbean	B3	7.08%	14.11%	9.51%
Suriname	Central and South America	Caa3	10.90%	19.23%	14.63%
Swaziland	Africa	B3	7.08%	14.11%	9.51%
Sweden	Western Europe	Aaa	0.00%	4.60%	0.00%
Switzerland	Western Europe	Aaa	0.00%	4.60%	0.00%
Taiwan	Asia	Aa3	0.65%	5.48%	0.88%
Tajikistan	Eastern Europe & Russia	B3	7.08%	14.11%	9.51%
Tanzania	Africa	B2	5.99%	12.64%	8.04%
Thailand	Asia	Baa1	1.74%	6.94%	2.34%
Togo	Africa	B3	7.08%	14.11%	9.51%
Trinidad and Tobago	Caribbean	Ba2	3.28%	9.00%	4.40%
Tunisia	Africa	Caa2	9.81%	17.77%	13.17%
Turkey	Western Europe	B3	7.08%	14.11%	9.51%
Turks and Caicos Islands	Caribbean	Baa1	1.74%	6.94%	2.34%
Uganda	Africa	B2	5.99%	12.64%	8.04%
Ukraine	Eastern Europe & Russia	Ca	13.07%	22.15%	17.55%
United Arab Emirates	Middle East	Aa2	0.54%	5.32%	0.72%
United Kingdom	Western Europe	Aa3	0.65%	5.48%	0.88%
United States	North America	Aaa	0.00%	4.60%	0.00%
Uruguay	Central and South America	Baa2	2.07%	7.38%	2.78%
Uzbekistan	Eastern Europe & Russia	Ba3	3.92%	9.86%	5.26%
Venezuela	Central and South America	C	17.50%	28.09%	23.49%
Vietnam	Asia	Ba2	3.28%	9.00%	4.40%
Zambia	Africa	Caa3	10.90%	19.23%	14.63%

ANNEX D

Novo Nordisk S/A

Semaglutide (Ozempic) US Patent Valuation

Firm-Wide Weighted Average Cost of Capital (WACC)

Valution Date: 31/12/2023

Thousands of Dollars

Assumptions				*Footnote:*
Valuation Date			31/12/2023	
Cost of Equity				
Risk Free Rate	Rf	=	4.6%	(1)
Unlevered Beta	Bu	=	0.53	(2)
Gearing	D/E	=	22.1%	(3)
Relevered Beta	BL	=	0.62	(4)
Equity Risk Premium	ERP	=	4.6%	(5)
Size Premium	SP	=	0.0%	(6)
Country Risk Premium	CRP	=	2.0%	(7)
Company-Specific Premium (Alpha)	A	=	0.0%	
Cost of Equity	**Ke**	=	**9.4%**	(11)
Cost of Debt				
Cost of Debt before Tax	Kd(pt)	=	5.3%	(8)
Effective Tax Rate	t	=	22.3%	(9)
Cost of Debt after Tax	**Kd**	=	**4.1%**	(10)
Financial Structure				
Debt-to-Total Capital	**Wd**	=	**44.1%**	
Equity-to-Total Capital	**We**	=	**55.9%**	
Weighted Average Cost of Capital (WACC)			**7.1%**	(12)

Footnotes

(1) Risk-Free Rate assumed to be equal to the Spot rate of 10Y U.S. Treasury Bond at December 31, 2023.
(2) Unlevered Beta (BU) calculated based on the Hamada formula from the Bottom-UP Beta approach.
(3) Average Industry Leverage Ratio based on the panel of comparable companies that operate in the GLP-1 market.
(4) Levered Beta calculated based on the Hamada formula considering the target industry gearing and the weighted average tax rate based on the revenues geographic segmentation.
(5) Based on Damodaran U.S. ERP estimates
(6) Negligible Size premium as the Market Cap of the Company is beyond the scope of the Size Premium.
(7) Country Risk Premium accounting for the firm-wide international operations, thus computed as the weighted average CRP based on the revenues geographic segmentation.
(8) Cost of Debt derived from the sum of the U.S. risk free rate and a synthetic credit spread based on the Company's Interest Coverage Ratio as of FY2023.
(9) Effective tax rate based on the eighted average tax rate based on the country's contribution to the firm-wide total revenues.
(10) rd = (Kd(pt) * (1 - t)
(11) re = Rf + B * (ERP) + SP + CRP + A (Expanded CAPM)
(12) WACC = rd * (Wd) + re (We)

Novo Nordisk S/A

Semaglutide (Ozempic) US Patent Valuation

Bottom-Up Beta

Valution Date: 31/12/2023

Thousands of Dollars

Hamada Formula:
Unlevered beta (Bu) = [BL / [1 + Wd/We * [1-t]]
Relevered beta (B) = Bu * [1 + Wd/We * [1-t]]

Company	Primary Ticker	Currency	Levered Beta (Raw Beta) (2)	Levered Beta (Beta Adusted) (2)	Gross Debt (Md) (3) +	Minorities (Mi) (3) +	Preferred Equity (3) -	Cash & ST Investments (3) =	Net Debt (Md) (4)	[(Share Price (3) x	Outstanding Shares (3)) =	Market Capitalization (5)	Total Capital (TC) Md + Me	Debt-to-Total Capital (Wd) = (Md/TC)	Equity-to-Total Capital (We) = (Me/TC)	Leverage Ratio (D/E)	Effective Tax Rate (t) (6)	Unlevered Beta (Bu) (7)
Eli Lilly and Company	NYSE:LLY	USD	0.60	0.73	26,467.3	91.8	0	3,041.5	23,517.6	582.92	899.3	524,224.2	547,741.8	4.3%	95.7%	4.5%	25.8%	0.58
GSK plc	LSE:GSK	GBP	0.61	0.74	18,018.0	(552.0)	0	5,688.0	11,778.0	14.50	4,076.1	59,112.3	70,890.3	16.6%	83.4%	19.9%	25.0%	0.53
Sanofi	ENXTPA:SAN	EUR	0.64	0.76	18,423.0	313.0	0	8,710.0	10,026.0	89.76	1,253.9	112,549.3	122,575.3	8.2%	91.8%	8.9%	25.8%	0.60
Merck KGaA	XTRA:MRK	EUR	0.38	0.59	9,941.0	75.0	0	2,413.0	7,603.0	144.10	434.8	62,651.5	70,254.5	10.8%	89.2%	12.1%	29.9%	0.35
Pfizer Inc.	NYSE:PFE	CHF	0.79	0.86	63,434.1	230.7	0	10,685.7	52,979.0	24.24	5,646.4	136,885.5	189,864.5	27.9%	72.1%	38.7%	25.8%	0.61
Bristol-Myers Squibb Company	NYSE:BMY	USD	0.63	0.76	41,521.0	55.0	0	12,280.0	29,296.0	51.31	2,034.8	104,403.4	133,699.4	21.9%	78.1%	28.1%	25.8%	0.52
Johnson & Johnson	NYSE:JNJ	USD	0.47	0.64	30,432.0	0.0	0	22,927.0	7,505.0	156.74	2,407.3	377,316.9	384,821.9	2.0%	98.0%	2.0%	25.8%	0.46
AbbVie Inc.	NYSE:ABBV	USD	0.48	0.65	60,579.0	37.0	0	12,816.0	47,800.0	154.97	1,765.5	273,605.3	321,405.3	14.9%	85.1%	17.5%	25.8%	0.42
Takeda Pharmaceutical Company Limited	TSE:4502	USD	0.42	0.61	36,934.0	4.8	0	2,045.7	34,893.1	28.76	1,568.9	45,121.0	80,014.2	43.6%	56.4%	77.3%	29.7%	0.27
AstraZeneca PLC	LSE:AZN	EUR	0.79	0.86	26,823.5	20.8	0	5,301.5	21,542.7	122.15	1,549.9	189,324.8	210,867.5	10.2%	89.8%	11.4%	25.0%	0.73
Industry Average														**16.1%**	**84.0%**	**22.1%**	**26.5%**	**0.51**
Industry Median														**12.8%**	**87.2%**	**14.8%**	**25.8%**	**0.53**

Relevered Beta - Hamada

Unlevered Beta (Bu)	0.53	(8)
Optimal Debt-to-Equity (Wd/We)	22.1%	(9)
Effective tax rate (t)	22.3%	(10)
Relevered Beta (B)	0.62	(11)

Footnotes

(1) Sourced from Bloomberg
(2) Adjusted Beta using the Blume Formula: B_Adj = 2/3 * Beta_Raw + 1/3 * 1
(3) Sourced from S&P Capital IQ
(4) Net Debt includes: Gross Debt + Minorities + Preferred Shares + Cash & Short Term Investments
(5) Share Price multiplied by the number of Outstanding Shares
(6) Tax rate based on the effective tax rate of the company headquarter
(7) Unlevered beta (Bu) computed based on Hamada formula:

$$\text{Unlevered Beta} = \frac{BL}{[1 + Wd / We * [1-t]]}$$

(8) Base on the Industry's Median of Unlevered Betas
(9) Based on the Industry Average D/E
(10) Unlevered Beta (Bu) based on industry average gearing (D/E)
(11) Relevered beta (B) computed based on Hamada formula:

$$\text{Relevered Beta} = Bu * [1 + Wd / We * [1-t]]$$

ANNEX E

ANNEX F

Novo Nordisk S/A

Reformulated Income Statement

Million of Dollars

	FY2019 Historical	FY2020 Historical	FY2021 Historical	FY2022 Historical	FY2023 Historical
TOTAL REVENUES	**18,325**	**20,863**	**21,536**	**25,424**	**34,444**
Growth %		***13.8%***	***3.2%***	***18.1%***	***35.5%***
Cost of goods sold	(2,480)	(2,931)	(3,056)	(3,502)	(4,570)
% on Total Revenues	-13.5%	-14.0%	-14.2%	-13.8%	-13.3%
GROSS MARGIN	**15,845**	**17,932**	**18,481**	**21,923**	**29,874**
% on Total Revenues	***86.5%***	***86.0%***	***85.8%***	***86.2%***	***86.7%***
SG&A	(5,267)	(5,916)	(6,151)	(7,155)	(9,000)
R&D Expenses	(1,940)	(2,254)	(2,492)	(3,127)	(4,356)
Other Operating Income/(Expenses)	94	79	54	165	90
EBITDA	**8,732**	**9,841**	**9,892**	**11,806**	**16,607**
% on Total Revenues	***47.7%***	***47.2%***	***45.9%***	***46.4%***	***48.2%***
Impairment of Fixed Assets	(33)	(78)	(109)	(116)	(315)
Depreciation and Amortization	(817)	(867)	(812)	(942)	(1,081)
% on Total Revenues	-4.5%	-4.2%	-3.8%	-3.7%	-3.1%
EBIT	**7,882**	**8,895**	**8,970**	**10,748**	**15,211**
% on Total Revenues	***43.0%***	***42.6%***	***41.7%***	***42.3%***	***44.2%***
Interest Expense	(33)	(64)	(44)	(54)	(80)
Interest Income	10	55	35	34	159
Net Interest Income	(23)	(9)	(9)	(20)	78
Income / (Losses) from Affiliates	(21)	24	(4)	(27)	12
Other Non-Operating Income / (Expense)	(22)	(342)	400	(338)	250
Pension, ARO, and Other Finance Expenses	(525)	163	(320)	(441)	(29)
EBT	**7,292**	**8,731**	**9,037**	**9,923**	**15,523**
% on Total Revenues	***39.8%***	***41.9%***	***42.0%***	***39.0%***	***45.1%***
Taxes	(1,442)	(1,806)	(1,732)	(1,945)	(3,113)
% on Total Revenues	*-7.9%*	*-8.7%*	*-8.0%*	*-7.7%*	*-9.0%*
NET PROFIT/(LOSS)	**5,850**	**6,925**	**7,305**	**7,978**	**12,410**
% on Total Revenues	***31.9%***	***33.2%***	***33.9%***	***31.4%***	***36.0%***

GLP-1 and Diabetes Patents- Royalty Rates

Date of Contract	Licensee	Licensor	Description	Royalty Rate % (low range)	Royalty rate, % (high range)	Royalty Base
05/15/2000	Amylin Pharmaceuticals, Inc	Alkermes ControlledTherapeutics Inc	1. Grant the right to make, have made, use, import, offer to sell, sell and have sold Products [exendins (including AC2993), exendin agonists, GLP-1 and GLP-1 agonists. The initial Field Product shall be subjecy to the provisions of Section 4.3(d)(i) below].	3.50%	25.00%	Net Sales
09/25/1998	Biomune Systems Inc.	Medical Foods, Inc.	1. Grant the right to make, have made, use, distribute, license, sell, have sold or otherwise dispose of the NiteBite Timed-release Glucose Bar (TM), any enhanced or modified versions, and to use the patent rights, know-how, technology, trade secrets, processes, data, material, methods or other information to undertake such activities.	12.00%	12.00%	Net Sales
10/21/2002	SANKYO CO., LTD.	METABASIS THERAPEUTICS, INC.	1. Grant the right to obtain an exclusive license to anyone (1) New Back-up Compound [Back-Up Compound to CS-917 that is more suitable with respect to the Field, and/or has a better phannacokinetic and toxicological profile, than CS-917 or the Current Back-up Compound] discovered by Metabasis during the Discovery Period (the "License"), which License, should the Option be exercised as set forth in Section 3.2, will be granted pursuant to Section 6.1.1(b) of the Restated Agreement and	10.00%	10.00%	Net Sales
10/24/2005	AMYLIN PHARMACEUTICALS, INC., ALKERMES CONTROLLED THERAPEUTICS INC. II	ALKERMES CONTROLLED THERAPEUTICS INC. II, AMYLIN PHARMACEUTICALS, INC.	1. Grant the right to amend that certain Development and License Agreement dated May 15, 2000 relating to an injectable long-acting formulation of AC2993 (synthetic exendin-4), Amylin's second diabetes drug candidate.	5.50%	8.00%	Net Sales
12/01/1997	Genentech,Inc., Alteon Inc.	Alteon Inc., Genentech,Inc.	1. Grant the right to use and sell Licensed Products in the Field [shall mean all human pharmaceutical uses of all dosage forms of all Licensed Products, other than the Retained Rights as provided in Section 1.40. The "Field" shall include, without limitation, the treatment of diabetes and the complications of diabetes] throughout the Territory, and a co-exclusive license (together with Alteon) for each Party to make and have made Licensed Products in the Field in the Territory.	10.00%	15.00%	Net Sales
12/10/2018	CSPC Baike (Shangdong) Biopharmaceutical Co., Ltd.	I-Mab Biopharma (Shanghai) Co., Ltd.	1. Grant the right to carry out strategic cooperation on TG103 products [long-acting recombinant GLP-I Fc fusion protein injection (including related patents) developed by I-Mab Biopharma based on the technology of hyFc technology platform], and develop and commercialize TG103 products for the treatment of type 2 diabetes mellitus and all indications related to this product in the territory [the People's Republic of China]. 2. Grant to CSPC Group the exclusive license and right to use patented technology owned by I-Mab Biopharma [I-Mab Biopharma's patents of TG103 and related patents, and proprietary technologies [non-public technology and other information, including but not limited to concepts, discoveries, data, designs, molecular formulas, R&D plans, test and detection designs, test and test results, processes, test records, and data of chemistry, pharmacodynamics, toxicology, clinical, analytical and quality control, data analysis, reports and summaries]] during the valid term of this Agreement, so as to develop and commercialize the licensed compound(s) [a long-acting recombinant GLP-I Fc fusion protein; the molecular structure and sequence of the fusion protein are presented in the Annex I] and licensed product(s) [one or more pharmaceutical (including diagnostic) products, including or containing (1) TG103, alone or in combination with one or more of any and all other forms of active ingredients, current and future formulations , dosage forms and dosages, and methods of administration; or (2) any fragment (including antigen binding regions or sequences or portions), variations, improvements, modifications or derivatives thereof] within the territory.	5.00%	10.00%	Net Sales
12/24/2002	AMYLIN PHARMACEUTICALS, INC.	RESTORAGEN, INC.	1. Grant the right to acquire the assets from RESTORAGEN, INC. 2. Grant the right to utilize all patents, patent applications and pending patent disclosures owned by RESTORAGEN, INC. on the Closing Date that would be infringed by the development, manufacture, use, sale or import of Products (a pharmaceutical product the active ingredient of which is glucagon like peptide-1 (7-36) amide; and a pharmaceutical product the active ingredient of which is an exendin-3 or exendin-4 or an analogue or agonist of GLP-1 or an exendin-3 or exendin-4).	6.00%	6.00%	Net Sales
06/29/2024	TRUSTFEED CORP	Pinata Holdings Inc.	1. Grant the right to practice, use and fully exploit the Patents and Know-How, and all Improvements thereto, for the purposes of producing, manufacturing and supplying Products (1. Metformin Gummy; 2. Metformin Crystals/Effervescent; 3. Inhaled Sildenafil; 4. Inhaled Sumatriptan; 5. Oral GLP-1 Capsule (Semaglutide or Liraglutide)); and (b) distributing, selling and commercially exploiting such Products throughout the Territory.	10.00%	10.00%	Net Sales
08/22/2011	Santarus, Inc.	Depomed, Inc.	1. Grant the right to enter into a new commercialization agreement for GLUMETZA® (metformin hydrochloride extended release tablets), a product that has significant potential in the type 2 diabetes market.	26.50%	70.00%	Net Sales
Min				3.50%	6.00%	
First Quartile				5.50%	10.00%	
Median				**10.00%**	**10.00%**	
Average				9.83%	18.44%	
Third Quartile				10.00%	15.00%	
Max				26.50%	70.00%	

ANNEX H

Novo Nordisk S/A

Semaglutide (Ozempic) US Patent Valuation

Relief from Royalty Method

Valution Date: 31/12/2023

Million of Dollars

Relief from Royalty Method			FY2024	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031
Total Revenues Attributable to US Patent		(1)	**14,910**	**20,956**	**25,472**	**21,847**	**22,403**	**22,973**	**23,557**	**24,156**
Growth %				59.6%	40.6%	21.5%	-14.2%	2.5%	2.5%	2.5%
Pre-Tax Royalty Savings	10.00%	(2)	1,491	2,096	2,547	2,185	2,240	2,297	2,356	2,416
(Taxes)	25.8%	(3)	(384)	(540)	(656)	(563)	(577)	(592)	(607)	(622)
After-Tax Royalty Savings			**1,107**	**1,556**	**1,891**	**1,622**	**1,663**	**1,705**	**1,749**	**1,793**
Partial Period			1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Discount Period			0.50	1.50	2.50	3.50	4.50	5.50	6.50	7.50
Discount Factor	9.4%	(4)	0.96	0.87	0.80	0.73	0.67	0.61	0.56	0.51
Present Value of After-Tax Royalty Savings			**1,058**	**1,359**	**1,510**	**1,184**	**1,109**	**1,040**	**974**	**913**
Cumulative Present Value of After-Tax Royalty Savings			**9,147**							
TAB Factor		(5)	1.22							
Fair Market Value - US Patent			**11,204.5**							
Fair Value - US Patent (rounded)			**11,204**							
Remaining Useful Life (years)		(6)	**8.0**							

Sensitivity Analysis:

Discount rate \ **Royalty Rate**	7.0%	8.5%	**10.0%**	11.5%	13.0%
7.4%	8,413	10,216	12,019	13,822	15,624
8.4%	8,120	9,860	11,600	**13,340**	15,080
9.4%	7,843	9,524	**11,204**	12,885	14,566
10.4%	7,581	**9,206**	10,830	12,455	14,079
11.4%	7,333	8,904	10,475	12,047	13,618

Footnotes

(1) The revenues attibutable to the U.S. patent are assumed to not be charachterized by marketing costs. For more information concerning the revenues projection, please refer to Exhibit 3.0

(2) The royalty rate is based on the median of comparable GLP-1 and Diabetes' medication patent licensing agreements

(3) In line with the U.S. corporate tax rate at 25,8%.

(4) In line with the Levered Cost of Equity and consistent with the findings of Stegink, Schauten, and Graaf.

(5) Please refer to Exhibit 8.0 for the Tax Amortization Benefit Calculation

(6) Based on the remaining legal life of the U.S. patent, which is expected to have an expiration date as of December 31, 2031.

ANNEX I

Novo Nordisk S/A

Semaglutide (Ozempic) US Patent Valuation

Rule of Thumb - 25%

Valution Date: 31/12/2023

Million of Dollars

			FY2024	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031
Rule of Thumb - 25%	25.00%									
Total Revenues Attributable to U.S. Patent			**14,910**	**20,956**	**25,472**	**21,847**	**22,403**	**22,973**	**23,557**	**24,156**
Growth %				59.6%	40.6%	21.5%	-14.2%	2.5%	2.5%	2.5%
Earnings Before Interests and Texes attributable to U.S. Patent		(1)	**5,836**	**8,203**	**9,971**	**8,552**	**8,769**	**8,992**	**9,221**	**9,455**
EBIT margin %			39.1%	39.1%	39.1%	39.1%	39.1%	39.1%	39.1%	39.1%
Implied Royalty Rate		(2)	9.8%	9.8%	9.8%	9.8%	9.8%	9.8%	9.8%	9.8%
Royalty Payments attributable to the Licensor			1,459	2,051	2,493	2,138	2,192	2,248	2,305	2,364
(Taxes)	25.8%	(3)	(376)	(528)	(642)	(551)	(565)	(579)	(594)	(609)
After-Tax Royalty Payments attributable to the Licensor			**1,083**	**1,522**	**1,850**	**1,587**	**1,627**	**1,669**	**1,711**	**1,755**
Partial Period			1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Discount Period			0.50	1.50	2.50	3.50	4.50	5.50	6.50	7.50
Discount Factor	9.4%	(4)	0.96	0.87	0.80	0.73	0.67	0.61	0.56	0.51
Present Value of After-Tax Royalty Payments			**1,035**	**1,330**	**1,478**	**1,158**	**1,086**	**1,017**	**953**	**894**
Cumulative Present Value of After-Tax Royalty Payments			**8,951**							
TAB Factor		(5)	1.22							
Fair value - US Patent			**10,964.6**							
Fair Value - US Patent (rounded)			**10,965**							
Remaining Useful Life (years)		(6)	**8.0**							

Sensitivity Analysis:

Discount rate \ Profit Split ratio	19.0%	22.0%	**25.0%**	28.0%	31.0%
7.4%	8,939	10,350	11,762	13,173	14,584
8.4%	8,627	9,990	11,352	**12,714**	14,076
9.4%	8,333	9,649	**10,965**	12,280	13,596
10.4%	8,055	**9,326**	10,598	11,870	13,142
11.4%	7,791	9,021	10,251	11,481	12,712

Footnotes

(1) EBIT attibutable to the U.S. patent are dervied from the projection of the Pro-Rata Costs Items.

(2) The royalty rate is based on the 25% profit split between the licensee and the licensor, in this case the Licensor perpsective is taken, multiplied by each year EBIT margin.

(3) In line with the U.S. corporate tax rate at 25,8%.

(4) In line with the Levered Cost of Equity and consistent with the findings of Stegink, Schauten, and Graaf.

(5) Please refer to Exhibit 8.0 for the Tax Amortization Benefit Calculation

(6) Based on the remaining legal life of the U.S. patent, which is expected to have an expiration date as of December 31, 2031.