

DANISH PATENT AND TRADEMARK OFFICE

Life science

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Preface

Denmark has an innovative and researchintensive life science industry. This is partly due to the fact that Denmark has a strong research environment and that the public and private sectors invest in research and development within life science. This is crucial because it helps create innovative solutions that have value for businesses, growth, and society.

With exports of DKK 175 billion in 2022, the Danish life science industry is an important part of the business community. In recent years, industry has also experienced a strong development in value added and employment compared to other European countries during the period¹.

At the same time, international competition in the life science industry remains fierce. It is therefore crucial that Denmark focuses on how to improve companies' innovation environment in the future. Patents play a crucial role in this context, as they enable companies to protect their prod-ucts and achieve a return on their investments.

Therefore, a number of initiatives have been developed aimed at increasing companies'

use of patents. Among other things, a patent voucher scheme has been established, which provides companies with financial support in connection with their patent application process².

The Danish Patent and Trademark Office has chosen to prepare a number of analyses aimed at taking the temperature of the innovation power within the life science industry³. The purpose of the analyses is to shed light on the extent to which companies in selected countries in the life science industry use patents to protect their innovation.

The present analysis confirms that Denmark's life science industry has a position of strength in the patent area. The position of strength is primarily driven by a number of large companies that account for the majority of Danish patent applications within the life science industry. The results of the analysis also show that there is a large ecosystem of small, patent-active companies in the Danish life science industry. The analysis also highlights the challenges SMEs face when trying to translate their research into patents.

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Introduction

Denmark has a strong life science industry that research, develops, and produces medicines and medical devices for patients around the globe. With exports totalling DKK 175 billion in 2022, it is one of the country's largest export industries, employing more than 50,000 people in Denmark⁴. It is also one of the strongest sectors in the area of patents.

The life science industry builds its research and innovation on patents. The development of new innovative medicines is often a lengthy and expensive process with a high risk of failure – even late in the process. Therefore, the patent system must ensure companies can get

⁴ The Ministry of Industry, Business and Financial Affairs (2023) '*Life science-industriens økonomiske fodaftryk'* ('*Economic footprint of the life science industry'*)



a return on their investment when they place the product on the market. This is crucial for incentivising investment in the research and development of new products.

The Danish Patent and Trademark Office has analysed the innovativeness of the Danish life science industry based on patent activity. The analysis reveals the trend in patent applications in the life science industry across selected countries to the US and European patent offices. The analy-sis provides an insight into developments and challenges in patenting life science technologies over the past ten years.

¹ The economic footprint of the life science industry (2023)

² Patent voucher (dkpto.dk)

³ The first analysis was prepared by the Danish Patent and Trademark Office in 2021. *Patent and Trademark Office (2021) Life science analysis.*

The patent system

The purpose of the patent system is to create incentives for the research and development of new products and to spread knowledge of new inventions to the public. For the life science industry, the patent system is crucial to incentivising investment in the research and development of new life science products. Life science products, especially medicines, are costly to develop and are associated with a high risk of failure during the development process. Therefore, it will limit the industry's incentive to invest in the development of new products if it is not possible for companies to protect their products and achieve a return on their investment.

The patent system also aims to spread knowledge of the patent to the public. To be granted a patent, a patent application must contain information about the invention and its function, which is published no later than 18 months after the patent application has been filed. This gives competitors and researchers, among others, the opportunity to be inspired by or further develop the original invention.

The patent system thus contributes to the further development of new innovative products by granting companies a time-limited exclusive right. This creates incentives to invest in research and development, while the exclusive right reduces the incentive to keep new knowledge secret from the public. Without the patent system, this knowledge can only be protected by keeping information about inventions secret.

Patenting in life science

In the life science industry, patents are often applied for very early in the process that it is not yet known whether the research will lead to a finished product capable of being launched on the market. The medicine is developed through four clinical phases, and as a general rule, the patent is applied for in phase 1. The whole development and approval process typically takes 10–12 years, and the patent is already issued in phase 1. The patent's protection period is 20 years, which means that the patent typically has about 8-10 years left for investments to be recouped from the time the pharmaceutical company receives authorisation to sell the medicine (marketing authorisation). Therefore, there are special rules for medicines that extend the period of market exclusivity and thus the period for recouping investments. Through what are known as supplementary protection certificates, the patent protection period in some cases can be extended by up to five years, however, so that protection can be obtained for a maximum total period of up to 15 years from the granting of the first marketing authorisation for the product in the EU.

What is a patent?

- A patent is an exclusive right to commercially exploit a technical solution in the form of a product or a method for manufacturing a product.
- The exclusive right to the patent is limited to 20 years.
- Patents are geographically specified rights, meaning that patent protection is only valid in the country or region where the patent has been granted.
- The patent is published no later than 18 months after the application has been filed, so that anyone can be inspired by and further develop the invention.



The national and international patent rules are formulated in the light of two multilateral agreements in particular - the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the WTO and the Paris Convention under the World Intellectual Property Organisation (WIPO), which sets minimum standards for patenting with a view to greater global harmonisation.

TRIPS stipulates, among other things, that national patent rules may contain rules on compulsory licensing that restrict the patent holder's exclusive right by allowing third parties to exploit the patent holder's invention. The rules on compulsory licensing can be applied where required in consideration of important public interests, such as the supply of essential medicines.

At the European level, it is also possible to use compulsory licensing to exploit patents for the manufacture of pharmaceutical products for export to countries with public health problems⁵. However, this has never been put into practice. The European Commission has recently presented a proposal to introduce a centralised compulsory licensing instrument in the EU for crisis management.

Increased competition in life science

The patent system has come under increasing pressure in recent years to shorten patent life or allow access to patents before they expire. This pressure has arisen particularly against the backdrop of COVID-19, where the debate over patents and access to essential medicines became a key topic. At the same time, international competition in life science has intensified significantly over the past ten years, reflected in a significant increase in the number of patent applications from Asia.

Figure 1 and Figure 2 show the number of patent applications filed at the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) broken down into selected countries from 2012-2022. The United States

has been a leader, with more patent applications submitted to the EPO or USPTO from the US than from any other country in the analysis. There has also been a sharp increase in the number of patent applications from China. This is especial-ly true for patent applications from China to the USPTO, where there has been a sharp increase from 2020-2022.

By comparison, the number of patent applications from Denmark is the second-lowest in the analysis, whether measured in terms of patent applications to the EPO or to the USPTO. However, this figure should be seen in the context of the countries' populations, as illustrated in Figure 3 and Figure 4.





Figure 2: Life science patent applications to the USPTO broken down into selected countries from 2012–2022



Leading position for Denmark in life science

Figure 3 and Figure 4 show the number of patent applications to the EPO and USPTO broken down into selected countries per million inhabitants. This gives a picture of the relative strength of countries, adjusting for differences in population.

The results show that China has filed significantly fewer patent applications per million population than other countries in the analysis. Germany and Sweden are generally in the middle of the pack, while Denmark and Switzerland are in leading positions. The United States is in the

from 2012-2022



Figure 4: Life science patent applications to the USPTO broken down into selected countries from 2012-2022



middle of the pack when measured in terms of the number of patent applications to the EPO, but is more strongly placed in terms of patent applications to the USPTO. In general, the trend in the number of patent applications per million population has been stable for the countries over the period 2012-2022.

In the period from 2012 to 2022, Denmark has seen a 24% increase in the number of life science patent applications to the EPO and a 26% increase in the number of life science patent applications to the USPTO, per million inhabitants.

Figure 3: Life science patent applications to the EPO broken down into selected countries



Technological strengths

Figure 5 and Figure 6 show the number of patent applications to the EPO and USPTO broken down into selected countries and technological classes. The results show that patent applications from Denmark are broadly distributed across technological classes and not just centred around medicines. Looking at technologies in which Danish life science patent applicants file the most applications, biotechnology ranks significantly higher than both medicines and medical devices. Denmark also comes significantly higher than comparable countries in the analysis in terms of the share of applications in biotechnology. This may indicate that biotechnology is a particular Danish strength.



Figure 5: Life science patent applications to the EPO broken down into technological classes from 2012-2022

Figure 6: Life science patent applications to the USPTO broken down into technological classes from 2012-2022





The role of SMEs in life science patenting

Figure 7 shows that micro and small enterprises account for 69% of all patent applicants in Denmark in the life science industry⁶. Micro and small enterprises account for 44% and 25% of all patent applicants in Denmark respectively, while medium-sized enterprises account for 12% of all patent applicants in Denmark. This is particularly interesting in terms of investment potential - there is a large ecosystem of small, patent-active enterprises in the Danish life science industry.

However, Figure 8 shows that SMEs languish when it comes to the number of patents, with large enterprises dominating the market. Large enterprises account for 64% of all patent applications in the life science industry in Denmark, medium sized enterprises account for 6%, small enterprises for 11% and micro enterprises for 19%.

SMEs make up 99% of all enterprises in Denmark and are the backbone of the Danish business community⁷. This highlights the need for special efforts to be made to support SMEs' knowledge of – and access to – the patent system. For the same reason, with the IP Action Plan (2021), the Danish Government launched a number of initiatives aimed at small enterprises and entrepreneurs, including a strengthened awareness-campaign and the launch of a patent voucher scheme to provide SMEs with financial support to protect their research and development with patents.

Large enterprises account for the majority of patent applications

Figure 9 shows that Novozymes and Novo Nordisk are the two most patent-active Danish companies in the life science industry. Together, they account for 25% of all Danish patent applications in life science from 2012–2022, while the ten most patent-active Danish companies account for almost 50% of all patent applications in life science during the period. This indicates that life science is a concentrated industry, with large companies accounting for the majority of patent applications.

Figure 9: Top 10 list of the most active Danish patent applicants in life science over the period 2012–2022



⁶ Size of enterprise is defined as 'number of employees' as registered in the Central Business Register (CVR), where micro enterprises are 0–9 employees, small enterprises are 10–49 employees, medium-sized enterprises are 50–249 employees and large enterprises are 250+ employees

⁷ https://denstoredanske.lex.dk/Sm%C3%A5_og_mellemstore_virksomheder_(SMV

It is worth noting that there are also other industries in Denmark where the majority of patent activity is concentrated around a few large companies. In the green sector, the ten most patent-active companies account for 72 per cent of patent applications to the EPO. Vestas, Siemens and LM Wind Power alone account for 51% of all patent applications in the green sector to the EPO⁸.

Research converted into patents

Denmark has a strong research environment with high standards at its universities and good opportunities for public-private research initiatives. We invest more in research and development than many other countries globally, relative to our GDP per capita, but struggle to create value from our investments.

On the Global Innovation Index 2021⁹, Denmark ranks fifth in terms of investments in research and development, while we rank 11th when it comes to creating value from these investments. This puts Denmark in 9th place overall among the countries in the analysis, which is significantly lower than Sweden, in second place, while Switzerland tops the list.

Several international studies show there is a clear correlation between increased growth and companies' exploitation of IP rights such as patents, trademarks and designs. For example, IP-intensive industries in Denmark accounted for 29% of Danish jobs and 47% of Danish GDP in the period 2017–2019¹⁰. In terms of patentactive industries, it was just under 20% of Danish GDP and just under 10% of Danish jobs. Another study shows that SMEs that obtain IP rights are 21% more likely to grow in the following three years than SMEs without IP rights¹¹.

As described in previous sections, it is clear that the large life science companies which are the most patent active. The question is why smaller enterprises are not capitalising on the value of their inventions with a patent, especially when companies that take out patents are more likely to experience higher growth.

Barriers to SMEs

Danish and international studies show that SMEs experience a number of barriers to protecting their invention with IP rights. In particular, lack of knowledge, costs and the value of IP rights are highlighted as barriers.

In the following section, two questionnairebased surveys underpinning existing knowledge on barriers to the use of IP rights by SMEs are highlighted in particular. These are a Danish survey by Moos Bjerre and EUIPO's European SME Scoreboard¹² survey from 2022.

Lack of knowledge of IP rights

Lack of knowledge of IP rights is often highlighted as one of the greatest barriers to use of IP rights by SMEs. The Moos Bjerre survey (2022) shows that 48% of Danish SMEs have 'no' or 'limited' knowledge of IP rights and that 15% of Danish SMEs decline to register IP rights due to lack of knowledge. The EUIPO survey (2022) shows that 19% of European SMEs decline to register IP rights for the same reason.

In particular, small enterprises lack knowledge of IP rights in Denmark. Among companies

with 10-49 employees, 9% respond that they have 'no knowledge at all' of IP rights, while this is true for 17% of enterprises with fewer than ten employees and 22% of enterprises with 0 employees.

Costs

The EUIPO survey (2022) shows that many European SMEs feel that costs of registering IP rights are high. This applies to both registration at the IP offices and costs in connection with advice.

Similarly, the EUIPO (2022) survey shows that long case processing times and high litigation costs are the most common reasons why companies choose not to enforce their IP rights.

The value of IP rights

The EUIPO survey (2022) shows that around 35% of European SMEs decline to register IP rights for the same reason because they fail to see any value in doing so. This is supported by the Moos Bjerre survey (2022), which shows that 49% of SMEs do not feel that IP rights are relevant to their business.

⁹ WIPO (2021) Global Innovation Index

¹⁰ EPO (2019) IPR-intensive industries and economic performance in the European Union

¹¹ EPO (2019) High-growth firms and intellectual property rights

Conclusions

Life science is a Danish strength. In the period from 2012 to 2022, Denmark has experienced a 24% increase in the number of life science patent applications to the EPO and a 26% increase in the number of life science patent applications to the USPTO, per million population.

The industry consequently makes a notable contribution to Danish innovation and the Danish economy. The analysis shows that Danish life science companies perform well in the area of patents in comparison to life science companies in other countries.

At the same time, there has been a significant increase in the number of patent applications from China in the period 2020–2022, and China is now on par with the number of patent applications from Germany and Switzerland. China has thus speeded up its development of life science and represents a market – and a competitor – that Danish companies need to pay close attention to. However, it is worth noting that China still filed significantly fewer patent applications per million population than other countries in the analysis.

Novo Nordisk and Novozymes account for 25% of all patent applications in life science, and the ten most patent-active Danish companies account for almost 50%, meaning that Denmark has a relatively concentrated industry with the largest companies dominating the market. This also means there is potential to increase patent activity for smaller enterprises, resulting in a broader spread of patents and market share in the life science field.

In addition, we are currently seeing increased pressure on the patent system. Therefore, it is crucial to maintain a sustained focus on a strong and well-functioning system for the protection of IP rights at the national and international levels. This will encourage investment in innovation, research and product development, creating a favourable framework for future growth and jobs.

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