

# IP Rights for SMEs Developing AI-Based Clinical Diagnostic Methods and Tools

Developing AI-based clinical diagnostic methods and tools involves navigating a complex landscape of intellectual property (IP) rights. Companies operating in this field must carefully manage both the protection of their own innovations and the risk of infringing on third-party IP rights, particularly patents.

This guide provides an overview of best practices and guidelines for exercising due diligence regarding third-party patents, as well as strategies for safeguarding your own inventions.

## Understanding IP Rights in AI-Based Clinical Diagnostics

[Patents](#) protect novel inventions. In the context of AI-based clinical diagnostics, this includes methods, devices, and the functionality of software.

A granted patent gives its owner the right to prevent others from using the invention defined in the patent for 20 years from the date of filing of the application for the patent. In exchange for this right to exclude, the patent must disclose the invention in sufficient detail for a person working in the field to understand and be able to reproduce the invention.

While this guide focuses on patents, other types of IP rights are relevant in this field. For example, [copyright](#) protects software source code *per se*, and database rights may protect the contents of databases containing training data. [Trademarks](#) and [design rights](#) can also be relevant, protecting aspects such as brand identity and the physical design of an object.

[Trade secrets](#) also should not be forgotten. Trade secrets can be useful for protecting innovations that cannot be reverse-engineered, or where the cost of obtaining a patent is higher than the value of the patent.

## Due Diligence and Freedom to Operate

Patents can be thought of as a fence around a small area within a technical field. The owner of a patent can use the patent to prevent access to that fenced-off area without their permission. Sometimes permission to enter a fenced-off area will be granted by the owner, e.g. granting a licence, and sometimes the owner will try to prevent access to that area, e.g. suing for infringement of the patent.

It is essential to understand that a patent does not give its owner the right to use an invention—only the right to exclude others from using it. To use the fence analogy, it is possible to obtain a patent that fences-off an area partially or wholly inside someone else's fence. In the overlapping area, the owner of the broader fence can prevent you from using your invention and *vice versa*.

The biggest risk posed by third-party patents is the risk of being sued by a third party for infringement of their patent. If the case is lost, you may be required to pay substantial damages to the patent owner and may be required to destroy infringing products and stop offering infringing services, for example. Even if the case is won, the cost of winning can be high with high legal fees and significant time and effort spent on defending the case.

In other scenarios, it may be necessary to take a licence, which often means that a certain percentage of all sales of the product or service will be paid to the patent's owner.

The best way to avoid these issues is to exercise due diligence at an early stage of product or service development, when the direction of development can be more easily changed based on the existence of third-party patents. This kind of due diligence exercise is generally called "freedom to operate" or "FTO" for short.

## Conducting an FTO Analysis

The goal of an FTO analysis is to find relevant third-party patents that could prevent you from using or selling your own products or services.

An FTO analysis can never give an unequivocal all-clear—it is impossible to be certain that all relevant third-party patents have been identified, and answers to the legal questions of interpretation and infringement cannot be certain until a court has decided on them—but it can indicate whether a different route should be taken for product or service development, or whether certain changes should be made in a product or service before it is launched.

It is better to begin the FTO analysis early in the process of product/service development. If relevant third-party patents are identified, they can be more easily dealt with, e.g. by working around the technical area fenced-off by the patent, when the product/service design is still relatively fluid. At this stage, an FTO analysis provides a high-level overview of the patent landscape. This provides an understanding of the parties who are actively obtaining patents in the field and the kinds of inventions that they are obtaining patents for.

Later in the process of product/service development, a more targeted FTO analysis can be performed. This provides an in-depth analysis of relevant third-party patents based on a close-to-final version of your product or service. This later-stage analysis is used to determine the risk of infringing third-party patents and, if necessary, make last-minute changes to the product or service to try to avoid infringement.

## Protecting Your Own Inventions

As well as exercising due diligence with respect to third-party patents, it is also important to consider protecting your own inventions with patents.

A [joint study](#) by the European Patent Office and EU Intellectual Property Office found that, on average, startups that apply for trademarks and patents rights prior to their initial seed or early growth stages are up to 10.2 times more likely to successfully secure funding from investors. Other studies have highlighted that [patent filings are a strong predictor of growth in high-tech industries](#).

As mentioned above, a patent gives its owner the right to prevent others from using the invention defined in the patent in exchange for a sufficient disclosure of the invention. Patents can be used to protect methods, devices, and the functionality of software, for example.

There are legal limitations on the types of inventions for which patents can be obtained. Often these limitations are thought to prevent certain types of inventions being patented, e.g. software and AI algorithms. However, software implemented inventions, including AI, are generally patentable as long as they are applied to a technical problem.

Problems in the field of medical diagnostics are essentially always considered to be technical and therefore patentable. For example, a classifier, when used to determine the likelihood of a particular disease based on a blood sample, is patentable. An artificial neural network used in a heart monitoring apparatus for the purpose of identifying irregular heartbeats is patentable. An algorithm for controlling imaging or other diagnostic tools is patentable. A model for determining energy expenditure of a subject based on data obtained from physiological sensors is patentable.

Even an algorithm *per se*, without a specific application, can be considered patentable if it leads to an improvement in the underlying computer system, e.g. reduced memory usage.

Patents should be considered for all of your inventions, but especially for those that are visible in the product or service that you will sell, or those that can be reverse engineered. If it would be possible for a third party to learn the details of your invention from the product or service, then it is not possible to keep the invention secret.

Furthermore, since patents can have overlapping scope, obtaining patents for your own inventions may help to establish your freedom with respect to another party's patents if your patents also cover that party's products or services. In these scenarios, cross-licensing of patents is a common way to enable both parties to use their own inventions.

However, the cost of obtaining and maintaining patents is not cheap, typically tens of per invention, across the 20-year term of a patent. Patents are territorial, covering only a limited geographical area, e.g. a single country or region. It is often necessary to obtain patents in multiple countries or regions to adequately protect your market, which quickly adds cost to the process. Furthermore, the cost of enforcing a patent, e.g. suing a competitor for infringement, are often even higher. It is therefore important to properly consider whether a patent application is worthwhile before even beginning the process.

## Conclusion

It is essential for companies working in the AI-based clinical diagnostics space to manage the risk of infringing third-party patents and to protect their own inventions using the patent system, where appropriate. It is never possible to completely mitigate the risk posed by third-party patents, but exercising due diligence at an early stage can avoid significant costs caused by potential infringement of third-party patents. Protecting your own inventions helps to secure your market and may also be useful for establishing your freedom to operate. However, it should be remembered that a patent only gives you the right to prevent others from using your invention—it does not give you the right to use it yourself.

When investigating freedom to operate and filing patent applications for your own inventions, it is essential to work with a legally and technically qualified patent attorney. While patent are technical documents that describe the details of an invention, they are first and foremost *legal* documents that cannot be properly interpreted or prepared without the required legal expertise.

For more information about how high-growth SMEs can use IP rights, including patents, to their advantage, further economic studies can be found on the [European Patent Office website](#).



Michael Nielsen  
European & UK Patent Attorney  
European Patent Litigator

Partner, Berggren Oy  
[michael.nielsen@berggren.eu](mailto:michael.nielsen@berggren.eu)

Berggren is a leading European IP law firm headquartered in Helsinki, Finland. For more information and resources about intellectual property, please visit our website at [berggren.eu](http://berggren.eu).

**Interreg**  
Baltic Sea Region



Co-funded by  
the European Union



RESILIENT ECONOMIES AND COMMUNITIES  
**CAIDX**