

Trade Secrets Directive §

GeschGehG

Protection of Trade Secrets in the Biotechnology & Pharmaceutical Industry

Dear Ladies and Gentlemen in biotechnology and pharmaceutical industry!

With today's biotech and pharmaceutical networking, increased collaboration through joint ventures, outsourcing agreements between companies, and increasing employee mobility, life science companies need not only to understand how to protect their trade secrets in the future but also to know how they will be tried to enforce lawsuits against theft of trade secrets. This applies both to the role of the victim and of the accused, unlawful acquisition and unlawful use of others trade secrets!

The enormous claims for damages from known cases show the true value of trade secrets for life science companies. Therefore, the probability of legal disputes has increased significantly since the entry into force of the TRADE SECRET DIRECTIVE (EU) 2016/943, especially when the safety of these trade secrets and the substance of the company is at stake. Evaluations of court judgments in the sector show that in 90% of cases at least one of the accused persons was known to the trade secret holder. In 40% of these cases, a business partner has been involved. These figures underpin the good qualities of the law, which was created specifically to prevent the loss of know-how through insider knowledge.

With the increasing technological networking, the increasing number of cooperation and other relationships, the risk of injuries resulting from the desire and the necessity of the information exchange between the business partners increases. Reason enough for all companies to be concerned, as soon as a trade secret has been revealed, its asset for the trade secret holder has been lost forever. The business secrets asset may change during the research and development of advanced medicines. Its protection needs to be adjusted synchronously. This is influenced by the research results from the various development phases and the race between the competitors. Even a chance breakthrough by a company can therefore be like a chain reaction across the industry.

Patent protection for investments in research and development

This industry is by far one of the most research-intensive industries. Similar research-intensive are only manufacturers of computers or IT hardware and software developers. Other sectors, such as the automotive, aerospace and defense industries, have significantly lower research rates. The path from an active agent to the approved drug is a very lengthy and costly process. After an average development time of 12 years, only one in 5,000 to 10,000 substances will receive approval after extensive clinical trials!

Modern medicines, therefore, enjoy patent protection of 20 years. However, drugs must be patented at a very early stage of development as the inventor's intellectual property. Between patenting and patient availability, on average, there is an actual patent life of less than 8 years. The new Trade Secrets Directive now extends the previous scope for protection of know-how and can therefore significantly influence the corporate values in this industry!

Trade secret protection vs. patent protection

Not all companies in the division belong to the patent proprietors. In fact, it is the only two forms of intellectual property that can protect information – Patent Act and the protection of trade secrets according to the Trade Secrets Act. Should and must be chosen between the two? There are more differences than similarities in between.

The patent gives the exclusive right to exclude others from the manufacture, sale, use or import of a particular product or service if in exchange a full disclosure of the invention takes place. In return, the Trade Secret Directive protects study results, test reports, records, protocols, contracts, formulas, processes, research team name lists, or other business information that derives its commercial value from being kept secret and the company making reasonable efforts to do so remains.

A patent protects patentable information and qualifies patentability criteria. The Trade Secret Directive may itself protect patentable information and any other information that may increase the commercial value of the trade secret holder. Therefore, the same information can be protected by patents and the Trade Secrets Directive.

This is not only the starting point for startups to decide which or whether both forms should be used to protect information. Patents are publicized, but trade secrets are kept confidential. Therefore, there are some key differences to consider:

1. The patent protects new and useful inventions. The Trade Secrets Directive all information of economic value as a trade secret of a company!
2. The patent gives the patent proprietor the right to exclude others from producing, selling, using or importing the invention, whereas the Trade Secret Directive only protects against the misappropriation of a trade secret!
3. While granting a patent, the invention is public. In the case of the Trade Secrets Directive, this is not the case. Here the information remains secret. For the grant of the patent, the applicant must file a formal application with a subsequent examination at the Patent Office. This kind of formality does not exist in the case of the Trade Secrets Directive!
4. The duration of a patent grant is approximately 2 to 3 years. This is much longer than the Trade Secrets Directive takes time for its implementation and for the establishment of long-term maintenance in the company!
5. The patent is valid for 20 years. The duration in case of a trade secret according to the Trade Secrets Directive is unlimited!
6. The cost and expense of patents are higher than Trade Secret management and vary from country to country. The comparison is amazing with an increasing number of patents and countries!

With the application of the Trade Secrets Directive, companies can nevertheless protect their inventions, which would wait for patentability or fail with their patentability. Three very important differences are the following:

A: The Trade Secrets Directive has its power in the flexible applicability and its indefinite effectiveness. On a timeline, it protects from the emergence of an idea to the final waiver of the company on its secrecy. Above all, this means a high level of protection for the company, especially in the risky research and development phases!

B: While patent law primarily serves to promote the exchange of information, the Trade Secret Directive protects the company against theft of information. It aggravates the secrecy of information in the company and the exchange of information with business partners. It reduces the risk of insulting insiders!

C: The high lost patent filing costs can be reduced because of the extremely high number of failed approvals. The time of a patent filing could be adjusted by the application of the Trade Secrets Directive the maturity of a research work and thereby also extend the patent protection period to be exploited!

The overlapping of Patent Act and Trade Secrets Directive can be described as a kind of balance between disclosure and secrecy of information. Economists argue that protecting trade secrets according to the Trade Secrets Directive is an alternative to patent protection. Its position as protection for the economy, however, is better than the patent protection on the basis of the points discussed earlier!

The Trade Secrets Directive implementation in biotechnology and pharmaceuticals

Irrespective of the organization, there are decisive factors in the research and development of new preparations that make the organizational implementation of the Trade Secrets Directive simple. The

development of a substance, starting from the idea to successful approval, is based on a fixed procedure and at the same time follows the ethical and legal regulations. Regardless of whether these are innovative active substances or analog preparations, the approved end product can only be created if the entire process chain has been completely processed and correctly documented. The resulting records prove the proper procedure as well as the medical purpose of further studies up to admission. So far, their individual validity, especially for the supervisory and approval authorities, has been rated as important, as they always begin their investigations after completion of the final product and use the available, complete documentation.

However, with the Trade Secrets Directive, these data are not just of medical value. The new law now creates the opportunity to exploit the economic value of this information as well. It is important to understand that the individual building blocks and the resulting information represent a different value for the business secret holder. As a result, even failures in research work can represent an economic value for a company and have a legitimate interest in protecting it as a trade secret. What is the meaning behind it? Regardless of whether a positive or negative study result was achieved, the economic outlay, as well as the resulting findings, are solidified as know-how in a company. Ergo, even a collection of failures (e.g., in diabetes research) would represent a value-added know-how database that can save a company a lot of time and money in future ventures. Not protecting this know-how would be a lost asset, which would save startup time and investment in developing new medicines at the same time. The resulting damage in case of loss for the trade secret holder would be huge!

Classification of know-how as defined in the Trade Secrets Directive

For the purpose of simple explanation, we use the example of categorization of know-how for the failure and success of studies, graduated after the idea has been patented or not submitted. Another possibility would be to differentiate ideas for the preparation of analog preparations or innovative active substance. An authorization would also have the classification according to economic aspects, such as target groups of customers or a special client or specific industry. A good example is the use for military purposes or in the aerospace industry. It is also advisable to classify publicly known information in the protection concept required by law. For this, the knowledge from basic research would be very useful. After all, it is part of the training of researchers and therefore classified as public knowledge.

Collecting information in order to obtain legal status according to the Trade Secrets Directive

The defined research and development process is divided into different phases and studies. In order to fully meet the burden of proof, if necessary, we recommend paying close attention to the information from preclinical and clinical studies. What are possible parameters that can be identified as a trade secret in a single research project? Here are a few useful examples to help you understand: employees involved and their roles, as well as periods of activity in each stage of study, all sites and facilities included, laboratories and high-tech equipment including, computer workstations involved, business partners involved and business agreements, all written and electronic communication, access and requests to the study results in electronic and physical form, and much more... In order for the lawsuit to actually protect, however, regular maintenance of the entire protection concept is also required. How often such an entire process has to be repeated depends on the product portfolio as well as the changes in human resources and the involved business partners. Our recommendation is to carry out the entire process at least once a year for all research and projects.

How can we help you protect your know-how according to Trade Secrets Directive?

So that all aspects of the law can be taken into account, we have developed our own audit procedure. This is accompanied by the software solution ROBOTIC GRC|365. With the software we brought, we are massively

increasing the level of automation and enabling rapid and cost-efficient protection of know-how as a trade secret. Regardless of whether your research is dedicated to a particular industry or purpose, we create evidence that enables you to enforce claims for injunctive relief and claims in court in accordance with the law. ROBOTIC GRC|365 helps classify your trade secret and identify the business secret holders behind it. Subsequently, necessary protective measures are created and their correct implementation checked! All services can be provided cross-border and there is no need to license our technology! For a legal status you will receive from us the following documents in German and English language:

1. A description of the project scope for the legally compliant implementation
2. Classification of your know-how as a trade secret according to the definitions
3. Catalog of measures for implementation as a protection concept
4. Test reports on the actual implementation of the protective measures
5. At least 1TB volume of forensic data on insider knowledge
6. Protocols on all contract adjustments with internal and external trade secret carriers
7. Material for employee training. On request, support in the implementation of training
8. Other purpose-based evidence as a submission to the court



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