



Enablement - do you have enough data to file a patent application?

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To be patentable, an invention must satisfy the basic patentability requirements common to all technical fields: that is, the invention must be novel and inventive, i.e. non-obvious in comparison to the prior art, and industrially applicable. An invention must, however, also be supported by sufficient technical disclosure to enable a person skilled in the art to practice the invention over the full scope claimed without undue burden: A monopoly is only granted for a given period of time in exchange for a disclosure to the public how to make or use the invention.

To comply with the enablement requirement a patent application can provide experimental data showing how an invention works. Unfortunately, no simple formula exists for determining the number of examples necessary to satisfy the enablement requirement. The necessity for examples in a patent application generally depends on the claims' breadth and on the degree of predictability in the technical field. Chemistry and biotechnology are generally considered highly unpredictable fields of technology, whereas mechanics and electronics are more predictable. The broader the claim and the less predictable the technological area, the more experimental data is usually required.

To make things even more complex, the requirement for experimental data in patent applications varies considerably between different jurisdictions in the world. Thus, when patent protection is desired in several jurisdictions across the globe, it is important that your patent application discloses your invention in a manner that allows for a global patent strategy.

European patent law requires a detailed description of at least one way of carrying out the invention. A single example may be enough if it is plausible that

all variations of the invention falling within the scope of the claims will work. However, if the claims cover a broad field, the claims are usually only considered enabled if the patent application contains a number of examples extending over the whole area covered by the claims.

The test for enablement of a claimed invention according to US patent law is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent application coupled with information known in the art without undue experimentation.

An important difference between the enablement requirement of US and European patent law relates to the possibility of filing additional experimental data after the filing date for enablement reasons, i.e. to show that your invention actually works. In Europe, if the technical content of an application is judged fundamentally insufficient as of the filing date, it is not possible to remedy the situation by submitting further experimental data after the filing date of the patent application. The US Patent and Trademark Office (USPTO) is generally more lenient in this respect and the submission of additional experimental data after the filing date to enable the claims of your patent application is usually accepted by the USPTO.

Many Asian jurisdictions, including China, require even more experimental data to comply with the enablement requirement, particularly for broad claims in unpredictable technological areas. In China, for example, it is quite common that the claims of a patent application must be limited to the aspects of your invention for which the patent application as filed provides actual experimental data. Consequently, the expected scope of claims in the

Asian jurisdictions is often much narrower than can reasonably be achieved in for instance Europe and the US.

The requirement for sufficient disclosure does not mean that it is always necessary to include actual experimental results to demonstrate that an invention works as claimed. In certain situations, it may be sufficient to include a hypothetical example, a so-called 'paper example' provided that the skilled reader can follow this example and arrive at the claimed invention without undue burden. Problems may, however, arise if the hypothetical example does not in fact work as written, or if substantial variation from the protocol as written, amounting to "undue burden", is required to make it work.

For patent applications containing claims to a medical use or method of treatment comprising a compound, inclusion of experimental data to corroborate the effectiveness of the use is essential to patentability. The data must be sufficient to make credible the therapeutic effect. This does not mean that clinical data in humans is required at the filing date - experimental data obtained *in vitro*, *in silico* or in an appropriate animal model can be used to show an effect in the patent application.

Often, a first patent application, a so-called priority founding application, is filed initially describing your invention in as much detail as possible. Once you have filed your priority application, you have one year from its filing date, i.e. the priority year, to file further applications, which may contain additional experimental data, to support your invention. It is, however, essential that you are able to obtain sufficient experimental data within the priority year to sufficiently support your claims. If not, your patent application may face difficult prosecution and as a result thereof, have a decreased likelihood of issuing as a patent.

Deciding on the right time to file a patent application can thus be a very difficult decision. A decision must be made whether to delay filing until a substantial amount of data has been accumulated to support the invention and risk being 'scooped' by a competitor, or alternatively file early to secure a filing date ahead of the competition and risk the patent application being rejected for lacking adequate experimental support.

So, when do you have enough data to file a patent application? The answer is "it depends." The technical

field of the invention, the predictability of the technical field, the amount of data you are likely to generate within the priority year, the type of claims you wish to pursue and the scope of the claims all play a role in the amount of data needed to comply with the enablement requirement. We recommend that you discuss your invention with your patent attorney at an early stage of development to determine when to file your patent application. If you have any questions you are very welcome to contact your patent attorney at HØIBERG A/S.



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