

Know-how v. Patents, Prior User Rights Provisions, and Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.

Each research project with commercial interest must assess whether it is better to keep the results obtained as know-how or to protect inventions based on them by means of patents. In many cases the situation is complex and different aspects must be taken into account in order to make the right decision. Perhaps the most important question that must be asked in order to make this decision is the following: if the invention were to be kept secret, how long would it take competitors to reach it?

To answer the previous question, the holder of the results must take into account the possible leaks of information from the company, the mobility of the workers and, of course, reverse engineering on the marketed products that the competitors could carry out.

If one chooses know-how over patenting, despite the fact that a correct assessment has been made and the necessary precautions have been taken, it cannot be excluded that a third party not linked to the person who developed the technology in the first place may subsequently protect it by patents. Faced with this possibility, it is important that the holder of the secret secures their right to exploit the product or process.

In Europe, and in most countries, the third party's possible patent would be valid despite not having been the first inventor, since know-how is not part of the state of the art. However, most patent laws in European countries have user rights provisions to protect the first to exploit a technology.

This right prevents a patent owner from excluding anyone who in good faith has exploited a product or process, or made serious and effective preparations for its exploitation, from continuing or commencing its exploitation, provided that these acts precede the priority date of the patent. However, this right has very important limitations.

One of these limitations is the difficulty of proving sufficiently and reliably that the exploitation or serious preparations were actually taking place. It is common for companies that secretly exploit products and processes to secure evidence of such exploitation by notarial deposits or similar methods, such as the French Soleau Enveloppe, which allow dating of previous use.

Another important limitation of the prior user rights is that it is generally limited to the territory where the exploitation is taking place. Thus, for example, in Germany, the United Kingdom, France and Spain, it is not allowed to start exploitation after the priority of the patent, even if the company has already exploited the object of the patent in other territories. In other words, the prior user rights may be limited to certain territories, preventing the international expansion of the company that exploits a technology in secret. This is one of the most important risks from a business point of view when choosing to exploit in secret.

A recent decision by the US Supreme Court, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 17-1229, slip opinion at 8 - 9 (January 22nd, 2019), gives new value to these notarial deposits in certain situations. Despite the change in the U.S. system, with the introduction of the first-inventor-to-file system instead of first-to-invent system, according to this decision, selling or offering for sale anywhere, even in secret, is a precedent for U.S. patent applications,

and may be sufficient to invalidate a granted U.S. patent. In contrast, the mere internal use of a product or process in secret cannot be used against the validity of a U.S. patent.

Within this framework established by the entry into force of the AIA and the *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* decision, whenever possible, an attempt should be made to secure not only evidence of the internal use of a product or process, but also additional evidence showing the non-public sale or offering of the product or process.

There is no doubt that the position of a company that secretly exploits a technology, in the face of a possible infringement suit by a subsequent patent family owner, will be much more favorable if apart from the prior user rights in certain territories, it can argue against the validity of that family's U.S. patent.

This new context makes know-how more interesting for a company. It is easy to understand that a patent owner may prefer to negotiate rather than to sue a third party for infringement, which may be covered by a prior user rights. The risk for the patent owner would not be limited to the possibility of losing the lawsuit, but also to a possible claim for nullity in the United States based on secret sales or offers in other countries.