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WHAT IS A FREEDOM TO OPERATE STUDY AND HOW TO APPROACH IT?

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The patent infringement risk assessment, also called freedom-to-operate (FTO), is essential to understand the risk of infringing third party patents associated with the performance of any industrial or commercial act on a product, process or service of interest.

This analysis must be carried out irrespective of whether the product, process or service in question is protected by a proprietary patent, as this does not exclude the possibility that third party patents may be infringed and entail significant economic repercussions for the infringer. It should not be forgotten that a proprietary patent does not give the right to exploit the invention, but to prevent third parties from certain activities on that infringement. In other words, a patent is a negative right.

The freedom to operate analysis can be very complex and the definition of its scope is critical. Thus, after receiving a request for a freedom to operate study, it is necessary to determine which aspects of the product, process or service of interest should be addressed, bearing in mind that it is practically impossible to reduce the risk of infringement to zero and that the objective of the freedom to operate study should be to provide the best balance between cost and safety, depending on the particular circumstances of each case.

The scope of the analysis has to be defined on the basis of the information received about the project, taking into account the client's needs, such as, for example, the purpose of the study; the level of risk the client is willing to accept; the existence of similar products, processes or services on the market; the competitors involved; the litigiousness in the particular sector of the technology, among others. It is also important to know the possible start date of exploitation, especially if the development period is long, since patents that expire before that date cannot be infringed and are therefore irrelevant.

Once these factors have been considered, preliminary searches are usually carried out to check whether the analysis initially proposed is feasible with reasonable resources. Following these preliminary searches, adjustments can be made to the study approach, if necessary, for example, by narrowing the searches to more specific concepts or by first analysing patent families of certain competitors.

Another important aspect to be defined before starting the study is the territories of interest in terms of where competitors could manufacture and, above all, where the commercialisation of the invention will take place. It should be noted that there may be territories of interest that are not well covered by the available databases. For this reason, the study usually focuses on the most important territories of interest on a global level, e.g. covering PCT applications and European and/or US patent documents. In this way, if a relevant patent family is located, specific queries can be raised with local agents in those territories not adequately covered by the databases to confirm the possible existence of equivalents in those countries, their possible validity, and scope of protection.

Once the scope of the study has been agreed with the client, patent searches can proceed, which are usually carried out on public and professional databases.

In the framework of the infringement risk analysis, in many cases, aspects of the product, process or service that are in the public domain, i.e. that have been known for more than 21 years, either because they have been described in a patent or disclosed in any other way, are often identified first. The interest in identifying these aspects lies in the fact that they cannot be validly protected by a patent in force. This in turn allows the study to be narrowed down to those more specific aspects that could still be the subject of patent protection.

Patent documents retrieved from searches that include equivalents in force in the territories of interest are then analysed and an infringement risk assessment is made, including both literal infringement risk and equivalence infringement risk, or contributory infringement risk, if applicable.

Finally, when the analysis concludes that there is a risk of infringement of a patent family, it is important to explore possible actions to be taken. These actions basically include two types of actions: either try to modify the product, process or service to reduce the risk of infringement, or carry out a validity study of the conflicting patent in order to determine whether there are grounds to argue for its invalidity. In that case, depending on the strategy to be followed and the strength of the arguments, actions can be taken to prevent the grant of the patent or to invalidate it if it has already been granted, or to force the patentee to negotiate a licence at zero or reduced cost.