Freedom-to-operate: promises and pitfalls in patent searches

FTO analyses are crucial, particularly for the life sciences, says Heinz Mueller of the Swiss Federal Institute of Intellectual Property

Like most companies in high-tech and high-revenue branches, life sciences and pharmaceutical companies operate in an increasingly dense patent jungle, which is hard to penetrate. In fact, this thicket is growing denser and denser by the minute.

To be successful in the market, companies need to analyse the situation and find their way around obstacles or define tools to remove barriers that block their prosperity. In other words, they need their freedom to operate (FTO), also called freedom-to-practice, product clearance, infringement analysis, right–to-use, or patent due diligence.

In which cases should FTO analysis be conducted and at which stages in the innovation process?

The analysis of the patent jungle to define whether some patents block the way is the first step in the process to gain freedom to operate. It should always be conducted for any product or process before the product is commercialised. Even for so-called simple products, a product clearance is always necessary. FTO analysis is performed throughout several stages of the development phase.

Even an early stage FTO analysis, when the final product is not yet clearly defined, may make sense and can be a basis for management decisions, since it may allow to estimate the risk involved in investing considerable research and development money.

Another situation when FTO analysis becomes a necessity is before licensing out or in of a technology or a product. The questions then are whether the licensee has the right to the patent he claims and what the strength of the patent is. The latter might be important for the negotiation of fees and royalties to be paid. Furthermore, it must be part of the due diligence process conducted before acquiring technologies, including patents and/or companies or company mergers.

Patent search is unavoidable

The FTO process includes the FTO search in the patent literature performed by skilled patent searchers, the analysis of and expert opinion on the documents found, with an estimation of the risks by patent attorneys, and lastly, the 'go' or 'no go' management decision.

The FTO search is consequently the first crucial step on which all further steps are dependent. The quality of this search is essential for an optimal estimation of the risks and a deliberated decision on the measures to be taken, be it the need for designing around, licensing-in and cross licensing, respectively, or attacking the patent in question.

Completeness is all

Performing a high-quality FTO patent search means overcoming several crucial challenges. First, the definition of the search matter needs to be as precisely defined as possible—the higher the precision the better the result. Second, the search strategy must reflect the needs of the customer. Maybe only a specific detail of the invention needs to be analysed because the other parts have already been examined.

Third, the geographical scope of the search is essential for the outcome, ie, it needs to be taken into account whether countries have to be included that are not well covered in the databases intended for use, and whether alternative databases or search strategies should be considered. Fourth, often each and every document of complex patent families has to analysed separately and their legal status has to be checked, and finally, yet importantly, the results need to be presented in a form that is tailored to the individual customer's needs.

The customer should take over where the researcher stopped, avoiding redundancy of work and thus time and money. A complete picture of all risks involved needs to be presented. In general, the end user expects that the analysis will show that no patent is infringed. Conversely, the researcher and the patent attorney probably expect that the analysis will show that there might be a certain risk involved.

Ideally, the analysis will show where the risks are, allowing an estimate of the size of the risks and enabling the management to make goal-oriented decisions. The goal of an FTO search is not to find a single needle in the haystack but to find all needles. Even for highly skilled searchers it is impossible to find all needles—a residual risk will always remain. This residual risk has to be minimised as much as possible through a thorough and high-quality patent search and analysis.

Requirements for a high-quality FTO search service

High-quality patent information to be used for decision-making is only obtained by the use of substantial expertise and access to specialised databases. One of the challenges involved in the selection of relevant documents is the fact that every 14 seconds a patent or utility model is filed somewhere in the world today. This accounts for more than 2.2 million new documents every year. The majority of these filings will eventually enter the respective worldwide databases.

Furthermore, on the background of the rapidly rising flood of patent and utility model applications from countries such as China, South Korea or Russia, language barriers increasingly prevent the efficient search for, and retrieval and evaluation of, many documents.

Overcoming these obstacles is vital for assessing the significance of the found documents. One solution to the language problems are improved machine translation tools. Such tools exist already and work sufficiently well for certain language combinations.

Although these tools may be sufficient to provide the English speaking patent information searcher with an idea of the significance of a document written in, say, one of the languages mentioned above, the detailed description of the invention as well as the scope of the protection is usually only vaguely recognisable. The involvement of a human translator is essential for documents that seem to be significant. This can of course contribute significantly to the overall costs of FTO analysis.

Furthermore, new areas in the life sciences including bio-nanotech, systems biology and synthetic biology to name a few, as well as

ever more sophisticated search tools such as text mining, statistical analysis, full text searching and the many other different search approaches made available by professional databases, call for highly educated and trained information specialists.

First and foremost, however, the competence of staff is the key factor to bring about a quality service. The second most important element is ease of access and identification, which basically refers to how fast the service can be found and accessed. Almost as important is a timely delivery since timing is of the essence when using IP information for decision making.

The depth of the search and the amount of residual risk will depend on the sum of money the customer is willing to spend—in other words, the risk the company is willing to take. All of these requirements can only be met if a continuous and comprehensive communication between the customer and the searcher is established before, during and after the search process.

The specific requirements for FTO analysis for life science companies

The life sciences is a unique business in the sense that the development of a drug is a lengthy process and very costly, but may lead to a large profits. Due to these facts, patents are especially important for this industry and the patent thicket is accordingly dense.

One of the consequences is that FTO analysis should be performed in the R&D process as early as possible to avoid unnecessary research costs. Later in the development process, an FTO analysis covering the production process needs to be conducted.

Finally, before introducing the product to the market, product clearance should be ensured again. Thus, a repeat FTO analysis is essential for the sales launch to be smooth and secure.

Furthermore, the searches might be more costly for FTO analysis than for other technical fields because specialised and expensive databases often have to be used. These databases might be necessary for searching chemical structures or biomolecule sequences.

Additionally, the analysis of the retrieved documents could involve more effort and time as well. Yet the costs for a repetitively performed complex FTO analysis are negligible compared to the development and marketing expenses for a new drug. Investing enough time and money in an FTO analysis at the right stage of the development process might even save money and allow a barrier-free market entry after approval by the respective authorities.

In conclusion, FTO analyses are crucial to prevent future patent litigation, loss of time and money, and for the successful market launch of a product, particularly for the life sciences industry.

Although a residual risk will always remain, FTO analyses should provide the customer with a reasonably good level of security for his business and a possibility to plan for the future. **IPPro**

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