Role of Freedom to Operate in Business with Proprietary Products

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A comprehensive Freedom to Operate (FTO) analysis requires analysing all forms of valid intellectual property (IP) rights and associated agreements and contracts to ensure that development or launch of any particular product/process in a particular market, in a particular country does not infringe any IP right of third party. FTO opinion is usually a legal advice; however, R&D organizations engaged in frequent patenting may also need to develop their in-house capability for FTO analysis. This paper illustrates methodology for FTO analysis, limited to patent rights.

Keywords: Infringement, freedom to operate, doctrine of equivalents

Prior art search is the most challenging job in a patenting activity. The orientation of prior art search would depend upon a well-understood purpose for conducting such a search. The prior art search may be carried out for various reasons, such as, determining the (a) patentability of an innovation, (b) ground of patent invalidation, or (c) possibility to proceed with the research, development and/or commercial production, marketing or use of a new product or process. Research project proposals for all research projects should be, invariably, preceded with prior art search. This gives a clear idea to the investigators to choose a proper line of research. A very exhaustive prior art search may also be required after the research work is over to determine potential patentable claims.

Prior art for determining the patentability and invalidation of patent claims constitutes any type of public disclosure of the art, including patents, publications, books, posters, presentations in conferences, and prior public use. Prior art search for the development and/or commercial production, marketing or use of a new product or process is commonly termed as a freedom to operate (FTO) search. FTO is essentially a legal concept, which connotes absence of any third party valid intellectual property right (IPR) claims against a particular commercial operation.\textsuperscript{1,2} FTO search is generally focused on the country where the product is to be commercialized, and includes only un-expired patents and under-prosecution patent applications of the country. Thus, the result of FTO analysis is expected to ring an alarm bell or a signal of opportunity of marketing the product in focus, in that country. This is one of the inputs used by technology managers to take strategic decisions in relation to product/process launch or even initiate R&D for realizing a particular product/process. The early preparations for an FTO analysis are crucial, because they influence all that follows and, hence, determine the quality of product/process.

**FTO Search: Initial Preparation**

The foremost requirement of FTO search is a thorough understanding of (i) the field of technology and (ii) the reason for FTO search. Based on this understanding, a set of questions/keywords may be prepared for which the FTO search may be conducted. One must concentrate on building a good strategy of prior art search of patents. After assembling the piles of raw information and data, it is to be put in the appropriate format. Thus, picking up the right phrases, sentences and all relevant claims from patent documents in the resulting data is a very important step. Based on this exercise, the next dependent step is the analysis of FTO search. Analysing a FTO search involves big stakes if the purpose is to commercialize or manufacture a product/process based on the results of this analysis.

**Dimensions for FTO Search and Analysis**

A comprehensive FTO analysis may require analysing all forms of IP rights including patent, designs, trademarks and associated agreements and contracts such as licence contracts or material transfer

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agreements. However, the discussion in this paper is limited to FTO analysis in relation to patent rights only. The patent search shall involve searching of (i) all granted and active patents, (ii) all patent applications under prosecution, and (iii) all PCT applications which may enter national phase, in a particular territory/country. An FTO opinion consists of only valid and enforceable patents in a territory.

As such, in conducting an FTO search and analysis, it is important to bear in mind the limitations of patent rights, namely, (i) it is territorial, (ii) it provides 20 years of protection on the condition of due payment of maintenance fees on time to the patent office concerned, and (iii) it is limited in scope as decided by claims. However, with respect to FTO analysis, the scope of rights may further be determined by the written specifications and prosecution history.\(^1\)

**FTO Analysis: Methodology**

A systematic FTO analysis may adopt the following sequential steps:

**Understand the Product/Process**

In the initial step in the FTO analysis, precise nature of the technology itself should be well understood; whether it is a product, process, or combination thereof. To understand the nature of technology, it can be disassembled into its fundamental components, which are deconstructed. In the deconstruction phase of preparation for the FTO analysis, the FTO team and any other scientists, collaborators, or staff, work together to resolve the product/invention into the fundamental processes used to make it, the components that have gone into its construction, and any possible combinations of processes and/or components potentially pertinent.

**Identify Keywords for Search**

Prior art search for the FTO opinion must be structured properly. The keywords must be selected so as to include: (i) all the broad as well as specific terms identifying the invention in the claims, (ii) elements defining the utility and cause of invention, and (iii) synonyms, for example, bioreactor for bio-digester; four wheeler for car, etc.

**Identify the Databases for Search**

FTO analysis is always country specific, as patent is a territorial right. Thus, for the same product/process in two different countries, two different FTO analyses need to be carried out. Patent search for FTO opinion is a highly focused search and missing out a single valid patent could have disastrous consequences. It is therefore necessary that a combination of databases be used in the search so as to obtain all valid details.

**Know the Country-specific Statutes, Doctrines and Case Laws for Infringement**

What constitutes infringement may vary from country to country depending upon respective patent statutes, doctrines and case laws. As such, before the FTO analysis, one must be well aware of the possible infringement grounds in the concerned country as per statute, doctrines and case laws.

**Search Patent Related Prior Art**

Patent literature of the already existing closest product/process must be searched thoroughly. Patent search may be carried out using name of proprietor, its licensee, other interested parties, technology based company(s) with relevance to already existing closest product/process.

The most critical aspect of FTO opinion involves examining the searched patent documents. Patent search related to selected keywords in various search databases may result in thousands of patents, although, all the patents may not be relevant. For instance, the status of each short listed patent/patent application must be checked out as only valid and enforceable patents and under prosecution patent applications ought to be included in the FTO opinion. Subsequently, a preliminary scrutiny based on the abstract and claims of the patent needs to be carried out.

**Prepare FTO Opinion**

A proper template should be used to prepare the FTO opinion. The FTO opinion must encompass all the information regarding each patent, independent claims of the patent, and methodology adopted for searching (Internet sites visited with date, keywords list, etc).

The product/process should be analysed in terms of each independent claim. However, the independent claims must be construed properly in the light of dependent claims, specifications and prosecution history (if required).

**Claim Analysis**

1. Bifurcate the claim into maximum possible elements defining the scope of the claim
2. Read the description of each element from the specification to understand the scope of element
3. Refer all the dependent claims
4. Broaden the claim to its maximum scope based on specifications and dependent claims.
5. Refer to prosecution history of the patent to analyse any possible infringement.
6. Dissect the product/process in question into fundamental components and analyse each component over the construed claim.
7. Determine if the product/process infringes claim.

**Infringement Analysis**

The product/process may be inferred to infringe the claim: (i) literally, if all the components of the product/process are covered by the elements of the claim, (ii) under doctrine of equivalents, if the product/process seems to be close to the claimed invention but the claim does not literally cover the product/process or (iii) by induced infringement or contributory infringement.

**Literal Infringement**

Taking into account each claim of the product/process in question, every requirement of each claim must be considered to see if each element set out in the prior art claim also appears in the product/process. If one or more elements set forth in a prior art claim are not present in the product/process being reviewed, there is no infringement of that claim. On the other hand, if each element which is set out in even one claim of the patent is present in the product/process, then there is direct and literal infringement. When literal infringement is found, it is normally the end of the inquiry.  

**Infringement under Doctrine of Equivalents**

The doctrine of equivalents is a legal rule in patent systems that would allow a court to hold a party liable for patent infringement and even though the infringing device or process does not fall within the literal scope of a patent claim, it is nevertheless, equivalent to the claimed invention. In the United States, there are two tests for determining whether an accused device or process is deemed to be equivalent. Under the first test called the ‘triple identity’ test, something is deemed equivalent if it performs (i) substantially the same function, (ii) in substantially the same way; and (iii) to yield substantially the same result. Under the second test, something is deemed equivalent if there is only an ‘insubstantial change’ between each of the elements of the accused device or process and each of the elements of the patent claim.

Besides, these, it is also necessary to evaluate indirect infringement, viz., induced infringement and contributory infringement.

**Analysis of FTO Opinion**

Preparation of an FTO opinion includes the steps of searching relevant patents, scrutinizing them as per their relevance and then analysing each prior art patent over the projected product/process. Analysis of the FTO opinion is a crucial step. However, it may be noted that no FTO analysis can be carried out with total certainty and that the FTO analysis in essence, only helps in reducing the risk of third party infringement suits. There could be two resulting scenarios: 1) product/process does not infringe patent rights of third party and 2) product/process infringes patent rights of third party.

**No Infringement**

If there is no infringement, the interested party may go ahead with the desired work. However, even after the launch of the product/process, the patent search must be continued for another 18 months because, there is a possibility that there may be filed patent applications that were not published at that time of carrying FTO analysis and may be relevant at the time of launch.

**Infringement**

If there is/are infringement issue(s) then one of the following options may be relevant:

- Ignore the product/process for time being and wait till the hindering patent expires.
- **Design around Strategy**: Since the scope of patents is limited by claims, if one can manage to steer clear of the scope even due to a single element of the claim, one can proceed ahead with the product/process without the risk of infringement. Design around essentially means to invent an alternative to a patented invention that does not infringe the patent’s claims. However, the design around strategy must be a fool proof strategy wherein the risk of litigation is very low.
- **In-licensing, Cross Licensing, Compulsory Licensing**: In-licensing is a provision wherein the permission for commercial use of hindering patent/s is obtained under certain terms and conditions and is a partnership that develops between two companies that have shared intentions, goals.
or fields of interest. In-licensing is popular because it allows the expertise of each company to be used in a way that is beneficial. Further, the profit sharing that results between the two companies can be very lucrative. Cross-licensing is another mechanism which could be adopted to avoid infringement where two companies exchange licences in order to be able to use certain patents owned by the other party. It requires that the interested company has a well-protected patent portfolio that is of value to potential licensing partners. Request for compulsory licensing may also be filed as applicable, i.e., in case the product of infringed patent (as per the FTO analysis), is not available in the market in reasonable supplies or cost.

- **Validity Search**: Explore invalidation grounds for the hindering patent. If the company/inventor wishes to launch the product/process, patent validity/enforceability opinion must be prepared as a part of FTO opinion. A validity search could be conducted when litigation concerning infringement of a patent is on the horizon, and the defendant is trying to invalidate the plaintiff's patent. Validity search is an extensive patentability search. It is similar to a patentability search, but its purpose is to determine whether a patent already obtained on an invention is valid or not.

However, invalidating the claims of a hindering patent is a tedious job involving a lot of financial burden since: (i) preparing a patent validity opinion again is extensive and expensive, and (ii) in case, an infringement suit is filed and the defendant challenges the validity of asserted claims of the patent, then the burden of proof lies with the defendant. Also, the cost involved in litigation proceedings is huge.

In case, the patent has not yet been granted, a prior art search would reveal whether it would be granted or not. In the FTO opinion, the claim construction of each independent claim and analysis of the hypothetical product over the construed claim should be made and final inference of analysis should be mentioned. The end of FTO opinion should accompany the final analysis of FTO.

**Benefits of FTO Analysis**

There have been some substantial advantages of using FTO analysis as illustrated in the following case laws in the US. There are however, no corresponding illustrative examples in India.

**FTO & Damages: Case Laws in USA**

The US patent system does not necessitate carrying out FTO analysis before undertaking any commercial activity. However, one has a duty to take due care not to infringe a patent if one has come across the knowledge of any relevant patent. 35 USC 271, sets out the conditions for determining the infringement of any valid patent, whereas, 35 USC 284 sets out the amount of damages to compensate for the infringement. It further stipulates that the court may increase damages up to three times the amount found or assessed. Although, the statute does not prescribe any criteria for such increased damages, however, precedent establishes that a person having knowledge of an adverse patent has an affirmative duty to exercise due care to avoid infringement of presumptively, valid and enforceable patent. Willful infringement is a basis for increased damage. The United States Court of Appeals for the Federal Circuit (CAFC) since 1983 has emphasized the importance of obtaining the advice of a counsel to avoid a finding of willful infringement. This has been clearly brought out in *Underwater Devices Inc v Morrison-Knudsen*: ‘where, a potential infringer has actual notice of another’s patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing.’ Although, there is no certainty that an opinion letter by a patent attorney will always avoid finding of willful infringement, yet a well reasoned opinion of a patent attorney that undertaking of a commercial conduct will not infringe any third party’s patent rights, is one of the best ways to minimize the risk of increased damages. In the famous case of *Polaroid Corp v Eastman Kodak Company*, Kodak could avoid the finding of willful infringement, as Kodak had sought the services of a patent law firm to conduct patent clearance studies. It is another matter that the attorney’s advice simply turned out to be incorrect. The court determined that Kodak was infringing (though not willfully) Polaroid’s instant photography patents.

However, the standard set in *Underwater* changed with court ruling in *in re Seagate*. The Seagate ruling raised the standard for finding wilful infringement. It replaced the duty of ‘due care’
standard with an ‘objectively recklessness’. More importantly, the court ruled that there is no affirmative duty to obtain the opinion of counsel i.e. freedom to operate opinion.

The credible and legitimate defences to infringement, the design around and request for patent re-examination can help in avoiding the finding of wilful infringement. On the contrary, in the court ruling of Brad Peripheral Vascular v W L Gore & Associates suggested that reliance upon invalidity arguments, earlier rejected by USPTO, can lead to wilful infringement. To conclude, an opinion from a counsel skill remains one of the primary aids in avoiding wilfulness charges.

**FTO and Declaratory Judgment**

In an interesting case, India’s number one generic pharmaceutical company, Ranbaxy, wished to launch cefuroxime axetil in USA. Ranbaxy came across a US Pat No 5,847,118 owned by Apotex. Ranbaxy had used the same process for manufacturing cefuroxime axetil as was claimed in the Apotex patent. But in a thorough FTO analysis, Ranbaxy noticed one critical variation in the process of preparation. Ranbaxy’s process involves the use of acetic acid as highly polar organic solvent. The claim 1 of US patent also recited the terms ‘highly polar organic solvent’ but, in the description, acetic acid was not mentioned. Further, when Ranbaxy evaluated the prosecution history of this patent, it was revealed that the examiner during prosecution had raised an objection over the term ‘highly polar organic solvent’ as indefinite. In order to overcome this rejection, Apotex defined this term, and highly polar organic solvents of the Apotex patent were sulfoxides, amides and formic acid. Apotex also included these amendments as dependent claims. Therefore, Ranbaxy filed for a declaratory judgment that its process for manufacturing cefuroxime axetil does not infringe Apotex patent. Ranbaxy was able to prove the absence of literal infringement or infringement under doctrine of equivalence. In view of the properly carried out FTO analysis, Ranbaxy could put forth its claims and counter claims to the arguments of Apotex and was granted a declaratory judgment by the United States Court of Appeals, Federal Circuit. Ranbaxy could thus, protect its commercial interests with the help of a rigorous FTO analysis and the follow-up exercise. Ranbaxy continues to the tablet and suspension dosage forms of cefuroxime axetil with the approval of US-FDA, the drug regulatory body of US.

The above case highlights the importance of FTO search and its thorough analysis which may help other companies or other enterprises, like the Ranbaxy, to market their products in other countries without any fear of infringement of any valid patent or patent application under prosecution, of third party. An FTO opinion should be prepared at the very beginning of initiating R&D related to development and launch of any product/process. Planning for the development, production and launch of a new product is a matter of forecasting future market developments and also minimizing risk of infringement for third parties. FTO analysis may also help in countering the allegations of wilful infringement. Broadly, FTO analysis is recommended before initiating any work towards realizing a product/process on the basis of concept, putting a product/process in market of a specific country, and/or licensing in a product/process from third party.

**Conclusion**

An FTO analysis based on the search of patent literature, in many ways, is just the first step. If the patent search reveals that there are one or more patents that limit the freedom to operate, the organization/company will have to decide as to how to proceed. A thorough search and critically analysed FTO opinion strengthens the organization’s confidence. The patent search should be systematic, structured and documented properly. Scrutinized patents must be thoroughly analysed and the claims construed in the light of patent specification and prosecution history to assess infringement. Even where the conclusion of FTO analysis is ‘no infringement’, a regular update of FTO is necessary to rule out any issues in subsequently published patent applications. Purposeful anticipation and availing of the opportunity of entering the market through a defensive, legal route like ‘declaratory judgement’ also may be considered in favourable situations. On the other hand, if the infringement issues prevail then appropriate decision must be taken. Licensing provisions and/or detailing the commercialization of the product/process are safe ways to overcome infringement issues. Design around strategy should be chosen carefully as it may involve the risk of litigation. Therefore, one must take a wise decision in the matter of FTO opinions, considering all aspects such as the technical, economic and financial aspects, and the brand of the competitor.
References

14 In re Seagate Technology LLC, 497 F.3d 1360 (Fed. Cir. 2007).