

FTO

One of the essential points for companies in term of IP rights is “Do not infringe 3rd party’s valid patents with intention.”

In order to avoid these risks, it’s very important for the companies to conduct the FTO (Freedom to Operate) search before the big investment, that is before investigating the researches in the laboratory, developing a new product and entering markets with a new product.

Basically, an FTO analysis involves following four major steps:

- (1) To perform a search to identify others’ relevant patents and patent applications
- (2) To analyze whether the aimed methods, process and/or products may fall within the scope of the claims of said patents and patent applications,
- (3) To assess the patent status of said patents and patent applications, and
- (4) To evaluate the validity of patents and/or the patentability of patent applications in order to identify any potential IP risks

The types of inventions to be searched for FTO analysis include patents and patent applications relating to:

- (1) Aimed agent /compound,
- (2) Its formulation (DDS) and/or combination,
- (3) Its use, and
- (4) Its manufacturing process and the key intermediates

Even in case there is only one blocking patent owned by 3rd party, the product cannot be entered into the market without obtaining a license from the owner of the said patent.

<Specific Issues to be taken into accounts for FTO Search in Japanese pharmaceutical market>

In this regard, there may be high possibilities that;

- (1) A JP equivalent may have a different scope compared with that of US and EP due to the different patentability examination, especially on inventive step and enabling disclosure,
- (2) Since Japanese always prefer and are very conscious about the formulations, e.g. tablets and capsules, with better compliance in the field of pharmaceutical industry, there may be so-called Japan-only patent cases of the inventions relating to specific methods for manufacturing and particular formulations and the like,
- (3) It's very hard for the foreign persons to detect said patents as they cannot understand the inventions which are described only in Japanese, and
- (4) Besides, the damages for the infringement on Reach-Through invention was admitted before a High Court in Japan, that has never been happened in other countries..

Hence, it's inevitable for pharmaceutical companies to conduct the FTO Search for JP market.

In case you would have any questions or problems, please do not hesitate to contact us. We have much expertise on FTO Searches and opposition procedures and invalidation trials.