FREEDOM TO OPERATE (FTO) ANALYSIS

Source: extract from Best Practices handbook, BiC project

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Freedom-to-operate means not infringing the IPR rights (almost always patents) of others and not needing licenses -- that may be costly or unavailable -- for IP owned by third parties when commercializing the invention. For example, to use reagents (such as antibodies) in a commercial kit, one needs to agree with the provider that the use of the component in a commercial product is allowed. The cost may be different. Furthermore, one needs to make a survey that there are no existing method patents that would cover the use of the reagent in the same indication.

Best practices:

- Compare the invention (as a whole) against existing patents and patent applications preferably already before generating own IPR. Pay special attention to key components that you cannot replace (such as rare antibodies).
- While FTO surveys can be purchased from several external actors, initial searches made by the inventors themselves increases their knowledge of the state-of-the-art and helps in not becoming dependent of IP owned by others in future projects. Purchased FTO surveys tend to be expensive (>10.000 €) and come therefore too late, i.e. when the product design is relatively fixed already.
- An initial FTO study should preferably be performed already after the early phase, before proceeding to assay development phase, so that obsolete or non-commercially-available (for further commercial use!) components or sequences are not used accidentally.
- Gaps in FTO detected any time before patenting may help in addressing the issue in the laboratory and in the patent application. In some cases alternative, free-to-use reagents and methods can be employed. If not, proceeding to pursue patent protection requires strong reasoning.
- Hindrances for FTO detected during patent prosecution must also be taken into account when making decisions on the continuance. Ask your patent attorneys to also report suspected FTO issues in their reports. Although not perceived as hindrances for patenting, they can be significant hindrances for commercialization.
- The need for third-party licenses should be allowed only rarely and only for elementary patents in which case a license is needed by all competitors, too.
- Take into account the expiry date and territorial coverage of the FTO-restricting patents.

- Note that some assays (such as nucleic acid assays) and chemistries (such as labelling reagents) can easily be executed with alternative technologies and chemistries although not familiar to the researchers. In such a case, the non-commercial proof-of-concept experiments may be based on a protected assay principle or chemistry. The commercialization partner can then execute the assay using the techniques and chemistries they prefer.

Pitfalls:

- An invention with restricted FTO means that the potential licensee also needs to negotiate and pay for other licenses before being able to commercialize the invention.
- For some fundamental technologies, commercial licenses may be readily available. The license fees for manufacturing and selling IVD assay kits are, however, significantly high compared to in-house or non-clinical assays such as animal or food safety testing.
- FTO may be compromised from the get-go if existing Background material is further developed in a publicly funded project where the project agreement (or MTA) limits the commercial use of so-forming Foreground materials/data. While an industry partner may suggest to retain all the rights to materials the company is supplying for the project, including the possible improvements made, the national laws typically prohibit subsiding private property with public funds. This means that the research organizations cannot (even by agreement) automatically transfer the industrial parties the right to commercially utilize the Foreground, but utilization can be separately negotiated at a market value price. However, the industrial partners may be offered the right of first refusal, i.e., priority of entering into an agreement (at market price) before external companies have been notified or approached. Similarly to above, the commercial utilization of other reagents, materials or software used in a research project may turn out to be prohibited. All restrictions and the potential to later violate third party rights need to be identified and tackled before the project starts.