TIPS ON CONDUCTING A COMPETITION ANALYSIS

Source: extract from Best Practices Handbook, BIC project

To have commercial use, a novel IVD test needs to solve a true clinical problem and be backed-up by convincing evidence. But it also need somehow to be better compared to the competing approaches or add value to the existing testing sequence.

A. Alternative biomarkers and assay formats

- The competition analysis must span the entire spectrum of different approaches. Many diseases have multiple biomarkers due to the involvement of different biochemical pathways, and many biomarkers can be measured at different molecular expression levels.

B. Best practices to conduct your own competition analysis

- Describe the current practices (especially the golden standard) used as a routine in the clinic and their limitations.
- Conduct a literature search (both in scientific and patent databases) for alternative (competing) approaches to solve the above shortcomings. The search should include analysing all the alternative scientific and commercial applications for the same indication, irrespective of the biomarkers or technical platforms employed.
- It is important to recognize and describe the significant benefits of the new invention over the competing approaches. Acceptable advantages include, e.g.
    - Increased diagnostic sensitivity and specificity
    - Earlier diagnoses (less advanced diseases with less complications)
    - Earlier therapeutic actions (less costly treatment with better clinical outcomes)
    - Improved convenience and patient compliance (e.g. less invasive sampling which is also likely to result in cost savings)
    - Expected reduced number hospital admissions or length-of-stay
    - Cost savings in testing or other diagnostic procedures (by replacing or reducing more expensive testing and other procedures)
    - Decreasing the number of invasive or harmful procedures.

Encoding or hiding the exact solution allows communication on the non-confidential level (with care). An already filed patent application gives more freedom for the presentations but also postpones the feedback.

- If alternative applications do not exist, proceed with interviews of end users to ensure that the invention answers a topical and significant clinical question.
- Following the competition on regular (or even irregular) basis is important because new

methods are constantly invented and singular surveys may give a false impression of non-existing competition. (Note that new patent applications become public only after 18-months.)

- Once a patent application is filed, the Office Actions (OAs) from patent authorities often contain valuable analysis of alternative solutions to the problem to be solved presented in the patent application. Re-visit the competition and FTO analyses to confirm that the advantages of the new method remain over the patent examiner's findings. (At least once a year).

C. Be aware that

- Competing applications are sometimes not recognized even though they were for the exact same indication and had the same performance and practicability characteristics. This is mainly because they are executed on a different technical approach or using biomarkers belonging to a different molecular class.
- Knowledge of competing methods emerges also during the patent prosecution process. Evaluation of competing methods should be made each time the patent authorities identify applications with same technical effect. Suggested time point for thorough evaluation is before entering the international Patent Cooperation Treaty (PCT) phase (evaluation then being based on the novelty and patentability report for the priority patent application) and national phase (evaluation then being based on the International Search Report (ISR) and Written Opinion (WOISA) or (at the latest) International Preliminary Report on Patentability (IPRP) of the PCT phase). The same decision making criteria is to be used than before submitting the application, i.e., a clear and relevant competitive advantage must remain.

D. Avoid self-competition

Sometimes the own improvements made after an own patent application compete with the markers and methods protected by the application. The new design is typically no longer patentable when the inventive subject matter has become public after 18 months.

In research projects spanning multiple years, postponing of patenting in the early years is recommendable if there is a high likelihood that the invention will be further developed or supplemented later (unless you already can predict the future developments, which is not often easy in case of new inventions). This allows ensuring that the most optimal embodiments are protected and offered for commercialization. However, postponing patenting also postpones publishing and one should have a strategy in place to optimize the schedule. Involve a patent attorney in planning the patenting strategy.