INTELLECTUAL PROPERTY RIGHTS (IPR) –in early stage projects

Source: extract from Best Practices Handbook, BIC project

Most commercial partners will not consider licensing without respective intellectual property (IP) protection due to the competitive edge it provides. The existence of IP rights (IPR) is paramount also in the eyes of investors.

Furthermore, concrete IPR allows ensuring a share of profits to both the inventors and the research organization after the launch of the product, typically as a certain percentage of income from the sales (royalty). Also see the chapters where the agreements and business models are discussed in more detail.

A. Using patents as a source of information

It has been estimated that 70-85 % of information found in patent databases cannot be found elsewhere. Researchers that follow the patenting field will have a significant advantage compared to those who are not up-to-date on the newest directions of commercial development.

The information contained in patent publications on new methods and products is much more detailed than the one that can be found in scientific publications. From assay development perspective, patent publications can even contain direct product development tips since they often include solutions to special problems which would otherwise only become apparent after long time of use and would be difficult to resolve without knowledge of the issue. One can also track down the main competitors in the field based on the patent publications.

- You can use free patent databases (Espacenet by the European Patent Office and PATENTSCOPE by WIPO) on regular basis.
- Use your TTO for sparring for interpreting patent claims where needed.
- As Chinese and Korean patent applications are in continuous increase, use machine translations accessible free-of-charge directly from the patent database websites.
- The patent databases can be searched e.g. by keywords, inventor, applicants, and application numbers. Patent classification codes can be used in the more advanced searches.

B. Novelty of research

Producing new information will obviously have the highest impact on the society. Staying aware of what other academic (or commercial) groups are doing and taking prior art and state-of-the art into account already when planning a new project will help in ensuring high standard and pioneering research and avoiding studying again something that is known already.

Best practices:

- Carry out novelty searches utilizing both scientific and patent databases. Abstracts of relevant conferences also often give a small peek on the state-of-the-art. Searches made when planning a new project will help to ensure that one is not researching already known matter again. Searches should also be made during the research projects each time when significant new and potentially inventive results are established. The previously published materials are referred to as 'Prior Art'.
- Patent applications give a view of the direction where the development is going. A long and expensive product development process may only be apparent by a company's patent application.
- Patent applications also give a view of the possible partners or competitors.
- While the patent slang can at first feel like a foreign language because of the specific terminology and repetitive structure of the patent publication, one will get used to it.
- The purpose of the patent publication's repetitive structure and wording is applying patent protection for an accurately and detailed defined invention in a structured and standardized format, and one will get used to the patent slang quickly.
- A patent publication describes a solution to a technical problem, whereas a scientific publication is a more neutral research report. However, both describe an invention with sufficient detail so that a professional can understand and repeat it.
- Patent claims, especially the independent patent claims (claim 1 and others that do not refer to previous claims), will determine the patent's scope of protection. The dependent claims represent the different embodiments of the invention. Patent claims are interpreted literally, with the help of the definitions given in the specification section.
- Note that patent applications become public only after 18 months from the filing date (priority date).
- It is a good practice to do a complementary novelty search before entering the PCT phase.

C. Patenting versus publishing: alternative protection strategies for early phase inventions

In the university settings, publishing is an inherent part of the work. Scientific publications and patenting are not mutually exclusive but the order matters.

Most of the inventions that are declared in invention disclosures to the university are in a very early phase. Yet, there may be significant pressure to protecting before publishing. Innovation must, however, be appropriately balanced with proof to be amenable to patenting. In the above situation, the **exemplary strategies** for protection include:

1) Not pursuing for patent protection (due to lack of sufficient amount of verification data and scientific evidence)
2) Filing a provisional (or similar non-searched) patent application using the manuscript to be published and subsequently filing a PCT patent application within one year on the condition that proof-of-concept data has been established)
3) Filing a conventional patent application based on the manuscript to be published.

The **pros** for the above situations are:

1) You have followed the criteria you have set for protection of biomarker inventions.
2) You will save in patenting costs in the case the verification studies or establishing the prototype fails. The official fees for provisional (i.e., non-searched) applications are low. Involving a patent attorney will increase the costs but also the quality of the application.
3) The new test might turn out to be a commercial success early on (although this rarely happens).

The **cons** for the above situations are:

1) The invention cannot be protected after it has been published.
2) You will not have the official novelty and patentability reports to support the drafting of the PCT patent application and patent claims. You may end up in pursuing too wide or too narrow scope of protection without a proper chance to amend the application. This can result in high patent prosecution costs.
3) There is a chance that the verification and proof-of-concept data either do not support the application or remain missing. Prepare to terminate the application process.

Alternatives to tacking the above cons:

1) Move to the next case or see 2) and 3).
2) Use provisional applications only as an alternative to saying no, i.e. instead of strategy 1). Order a novelty and patentability survey or have the application searched at the patent office (you will need to submit patent claims with the manuscript). Proceed to filing a PCT application only in case the required (and convincing) data has been generated by the end of the priority year. As there has been a clear deadline (10-11 months) for the further proof, it is a simple decision whether to proceed with patenting or not.
3) Communication of expectations combined with preparing to alternative scenarios is important. Collaborating with researchers, proceed to filing a PCT application only in case the agreed data has been generated by the end of the priority year. As there has been a clear deadline (10-11 months) for the further proof, it is a simple decision whether to continue patenting or not.