SCOPE OF PATENT PROTECTION

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The most important characteristic of a patent is its scope of protection, which defines whether it can be easily circumvented or not - in other words, whether potential utilizers need a license for it or not.

Broad patent claims are especially important in the case of university-based inventions for which the motivation for patenting lies in technology transfer, that is, selling or licensing the IPR for companies for a fee. This approach significantly differs from that of the industry, where the primary aim of patenting is typically not out-licensing but protecting the existing or upcoming products and/or increasing the value of the enterprise.

From this perspective, some type of biomarker inventions are difficult to patent well.

Best practices:

- To ensure that the university-owned IPR becomes interesting to companies, it is not enough to have an invention patented – it needs to be patented well and with broad enough patent claims so that the scope of protection is proper for the technology. Companies will only pay for rights they really need.
- If the intention is to form a start-up, the viewpoint of protecting the planned products can be emphasized somewhat more.
- Also make a plan for the relevant territorial coverage of the patent family.

Things that are difficult to patent well:

- A weak patent is any patent that opens up the possibility for the potential utilizer to circumvent the patent claims by replacing the least meaningful limiting feature of the independent patent claim by another solution that works similarly well.
- Biomarker panels/patterns/signatures: The current evidence shows that many tests are likely to rely on multiple biomarkers in the future. It is, however, more complex to get regulatory approvals and solid patent protection for multiplex biomarker tests than the singular assays, as the more biomarkers that are required in the claim, the easier it will be for third parties to replace one or more of the biomarkers and thereby circumvent the patent
- Furthermore, the larger the number of markers in a combination, the easier it becomes to replace one marker with another (or several) outside the list. In the case only a pre-defined set of biomarkers ("signature") seems be patentable, preferably only the very top marker(s) absolutely needed for the method to work should be included in the independent patent claim(s). The remaining markers should be put in a priority order and

listed in dependent claim(s). If the inventors only have an unprioritized list of candidate biomarkers that work in several different combinations, unity of invention will certainly be an issue and it will be difficult to obtain strong patent protection. This is also to avoid a "lack of unity" objection, which is easily received from the patent examiners when claiming an unprioritized list of biomarkers that work in several different combinations.

- Sequences: Nucleic acid and protein sequences typically have room for minor adjustments especially around the key binding units. It is difficult to protect complex nucleic acid or peptide sequences so that all solutions that work in an assay would be covered. In the case of new biomarker findings, it is important to try to search options for protecting the new assay by the target, without strictly defining the actual binders. The exact sequences should only act as examples and be described in the dependent claims. This also applies to new antibodies against existing biomarkers. The commercial value of antibodies easily replaceable by other antibodies (with slightly different sequences) is very low relative to patenting costs. Patenting of antibodies and nucleic acid assays is feasible only when the claims permit covering virtually any binders for the same.
- Methods for production of diagnostic assay: When use of a patented production method is not evident from the diagnostic assay itself or its public documentation, infringements are difficult to monitor. The burden of proof is always at the IPR owner. The new method might result in significant savings in the manufacture of a specific product, but if the same could also be reached by other means, one could never be sure if the potential but reluctant client was already using the method or not.
- Patenting in the US: Due to a number of Court decisions over recent years, it is currently not possible to patent naturally occurring products in the US, such as naturally occurring nucleic acids, amino acid sequences and fragments thereof. It is defined by the patent authorities as "Law of Nature". It is however possible to patent variants of such naturally occurring products/sequences.
- In addition, it is also very difficult to patent diagnostic methods in the US unless the biomarker is measured by unconventional means and/or a post-solution activity is added to the claim, usually in the form of a treatment step with a specific drug (companion diagnostic claims).
- For all the above cases it needs to be noted that patent protection by research organizations is not pursued to ensure FTO of own products but the goal is in out-licensing. It is therefore very important that the patents cannot easily be circumvented because the customer is purchasing IPR, not the final product.