

## Screening Assays



Screening assays, whether based on receptors, enzymes or any other biological material, are essential tools for drug discovery research. Although the screening assays themselves and the different components used therein have commercial value, there is of course a much greater potential commercial value in the drug molecules and other therapeutic agents which are discovered and developed using such screening assays.

In the European Patent Office (EPO), a newly discovered drug target, such as a receptor or an enzyme, and a screening method based on that drug target, may be the subject of patent claims. The same applies to a screening method based on a newly discovered mode of action of a known molecule. These claims could prevent a competitor from using the screening method or supplying components of the assay, such as a kit or an enzyme.

However, such claims would not cover the therapeutic agents discovered by the screening method as these are not considered to be “products” of the claimed screening method.

In order to protect the future results of research enabled by the new screening method, a patentee would ideally want to claim all therapeutic agents discovered by the new screening method. This could be attempted by claiming compounds defined by their common function: their activity at the specific receptor. For example:

*A compound which binds to receptor Y for use in therapy.*

However, the EPO, and the UKIPO, do not allow these types of claims, mainly because their scope of protection would inevitably be much wider than the disclosure of the invention and would cover as yet undiscovered compounds, going beyond the “contribution” the inventor has made to the art (as happened in EPO Board of Appeal Decision [T1063/06](#)). Claims of this type could not be adequately supported by the disclosure in the patent application, and would also be considered unclear and to lack novelty, if any known compounds have such activity. Other important countries, such as the US and Japan, broadly follow this approach.

Therefore, therapeutic agents discovered using new screening assays must be specifically claimed in terms of their structure, in order to secure valid patent protection. Faced with such limited protection, some innovators may choose to keep their screening assays confidential rather than file patent applications, which will lead to their publication. Those that do file for patent protection face a decision of when to file during a research programme. If filed too early, they will not be able to obtain broad claims. If filed too late, they risk being beaten to the filing date by a competitor.

We have explained the general principles of handling inventions arising from new screening assays in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.