BioCurate

Fact Sheet

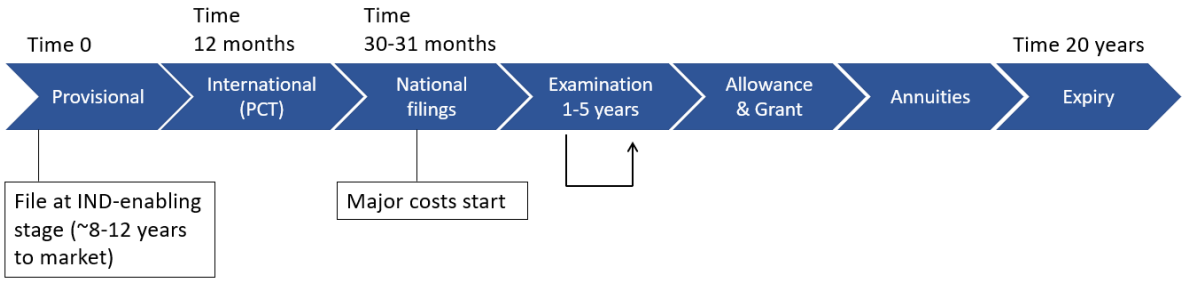
IP Protection and Patenting Strategy – BioCurate's perspective

Note: this is intended as a guide on general principles only, there are important aspects that may differ depending on modality or therapeutic area and investigators are encouraged to seek additional specific advice from an appropriate expert in the field.

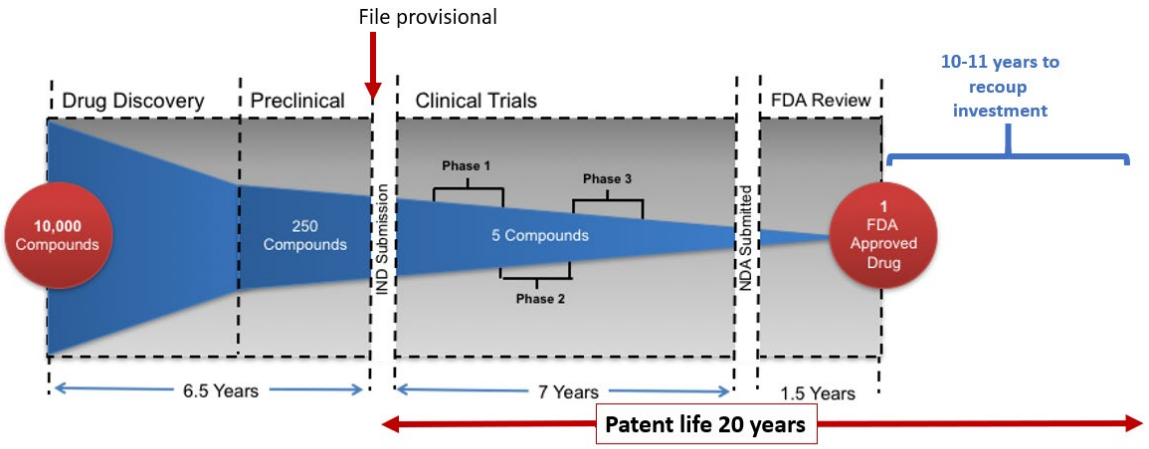
The aim of this document is to help investigators understand how to protect and maximize the value of their intellectual property (IP).

One of the key aspects of a project that any future investor or pharma partner / licensor will evaluate prior to making a decision to invest is the strength of its IP position. Drug candidates that have longer patent exclusivity periods remaining when first-in-human (FIH) studies are initiated are more likely to attract investment.

There is a 20-year timeframe from the point a provisional is filed until patent exclusivity expires, the key steps in the patenting process are illustrated in the diagram below:



The industry average time to take a small molecule project from target discovery to a marketed drug is ~15 years, ideally patent filings protecting the composition-of-matter would be made as close as possible to initiation of FIH studies as this would allow a 10-11 year period of remaining patent exclusivity at the point the drug was entering the market, illustrated below:



Industry average timeline & numbers

Quelle: Burrell Report Biotechnology Industry 2006

BioCurate

Note the above industry average timeline is for small molecule projects and this will differ for other therapeutic modalities (e.g. antibodies, cell therapies, gene therapies).

Public disclosures and prior-art

It is important to be aware that any public disclosure impacts the ability to get patent protection (claims granted). Public disclosures include seminars, posters, papers, abstract submissions, and presentations to any group beyond the immediate project team including verbal-only discussions. Any public disclosure will be used by patent examiners as prior-art and will result in rejection of patent claims. If discovered after granting of claims, prior art could lead to invalidation of the granted claims.

Once a patent publishes it becomes prior-art even to the inventors listed on the patent. For this reason, it is important not to file patents prematurely for a commercial project. If the patent is filed without the drug candidate being explicitly included in the filing it may be very difficult to obtain patent protection later on for the drug candidate due to this prior-art.

It is possible to achieve both commercialization and publication with careful IP management and BioCurate will work with investigators to develop a publication strategy at the outset of the project. With careful planning publications can add value to future commercial deals.

For further information on this, or any other topic related to the drug discovery and translation process, please email the BioCurate team on info@biocurate.com