

# REDL

## Life Science Patent Attorneys

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### About Biotech Patents

The aim of a biotech company is – no surprise - to own strong patents, and to work in a field that is not infringing third party claims. It is thus key to establish a patent portfolio of proprietary rights with an eye to third party patent claims, i.e. avoid patent conflicts early on or to obtain the respective licenses as needed.

There are a few specifics to consider when dealing with biotech patents and intellectual property (IP). IP plays a core role in all biotechnology companies; many early stage companies have few other assets and depend on strong IP to attract investment or partners. Investors are thus increasingly assessing the strength of IP portfolios in order to reduce the exposure to risk. Therefore, IP due diligence is considered a key driver of funding and deal making.

The existence of potentially blocking third party IP is a barrier to investment. Challenges of emerging competition need to be taken into account. In particular, the expansion of biotech patenting makes freedom-to-operate increasingly uncertain and difficult to ascertain. Some challenges to biotech companies refer to transfer of highly innovative technologies from academia to companies. Though technology transfer offices provide great support, it is not yet routine for European academia to transfer technology from the laboratory to commercial exploitation.

Since the biotech industry is relying on innovative technologies, it is not overly worried about biosimilars. It is obviously difficult to demonstrate that a true “generic” biologic exists. However, a key challenge remains in the lengthy development and regulatory approval process of biotech products.

While a company might be successful in gaining broad early stage patent protection, one has to face erosion of patent lifespan. Thus, obtaining follow-on patents and establishing a respective patent portfolio to prolong the patent life of products, is especially desirable from the biotech industry perspective.

Speeding up the patenting process may provide a significant tool to reward the innovator, supporting the investment case and business opportunity, and to clarify the freedom-to-operate and licensing needs. In many cases it is helpful to request accelerated examination, before the European Patent Office or national patent offices.

The public acceptance of European biotech IP is constantly improving. After a lengthy discussion throughout Europe, biotech patents are widely supported by EU guidelines. Research privileges allow for clinical studies and trials necessary to apply for marketing authorization, as exempted from patent infringement in most cases. Finally, data exclusivity periods are provided by regulatory agencies to provide safeguards for biologics manufacturers.

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