

## Selecting a Manufacturing Location

*A case study on freedom to operate for manufacturing an antibody.*

**Problem:** The client had developed a therapeutic antibody, suitable for human administration, but needed to select a manufacturing location. Several non-expired US patents meant that manufacturing was not possible in the US.

**Solution:** GAI evaluated the client's antibody, including the technology used to render it suitable for human administration, and determined that the relevant patents had expired in Europe. Various European countries were evaluated in terms of existing facilities that could produce the antibody; one European country was selected as a manufacturing location that both had the necessary manufacturing facilities and for which the relevant patents and their extensions had expired.

**Background:** Currently the US and other countries provide for a patent life of 20 years from the filing of a patent application; extensions may be granted for therapeutic products, based upon the length of time required to fulfill regulatory requirements. However in the US, older patents may fall under a rule which provides for an alternative patent life of 17 years from the date of grant, such that for some technological areas, one or more patents may still be non-expired in the US yet their equivalents may already have expired internationally, outside of the US.

**Challenge:** The client's antibody product was at a stage in the regulatory process in which the manufacturing location had to be finalized for producing the final product to be sold. However, a number of blocking US patents would not expire until well after the planned launch date of the product outside of the US.

**Outcome:** GAI reviewed the planned launch dates of the antibody product with the client in different countries, and determined that all of the initial launch countries would accept antibody products manufactured in the United Kingdom for regulatory purposes. Review of the relevant patents revealed that all of them had expired in the United Kingdom, including with regard to patent extensions.