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1. Licensing agreements – an option for a tailor-made biotechnology transfer

Biotechnological inventions are characterized by their broad application and high innovation potential as they can be implemented in a variety of products across different industries, e.g. pharmaceutical, agriculture, food, or environmental protection, and meet the primary needs of society, e.g. in the therapeutic sector. These promising marketing perspectives are an incentive for investors when evaluating a business partnership with the owner of biotechnological intellectual property. At the same time, business partners must travel a long and risky path to turn a first genetic research result or discovery into a registered and marketable product. In addition, as improvements in biotechnology occur at a rapid pace, it seems important to establish long-term business partnerships, which comprise the second and third product generations.

Licensing agreements are the most flexible type of business partnership between investors and biotechnology research units as they can be structured according to their individual cooperation scheme, taking into account their development and commercialisation capacities and interests. For example, a university, research institute or SME with research capacities may lack financial and human resources to develop products from its basic biotechnological inventions, or its business concept may not include the development of products. The licensee may have expertise in commercialising biotechnology and follow an investment strategy that provides the resources necessary to develop the basic biotechnology into a registered and saleable product.

2. Patent licensing and/or know-how licensing within a material transfer agreement

The main strategic decision to consider is whether the biotechnology invention should be patented, taking into account how broad and defensible a patent could be obtained. It is difficult to obtain patent protection for some products, such as monoclonal antibodies, due to the rapid development of the techniques for generating them. Furthermore, patenting requires making available the cell line that generates the monoclonal antibody and thus any unauthorised use of the cell line would have to be controlled by expensive and labour-intensive measures, possibly including patent infringement litigation.

On the other hand, some technological approaches can be designed around or avoided by similar approaches. Or a technology may be developing so rapidly that the invention is likely to be superseded before it can be patented. *Thus, instead of patenting and patent-licensing, in some cases, a mere material transfer arrangement that includes the licensing of (not patented) know-how with the transfer of the cell line or other materials concerned and a mutual confidentiality obligation may serve the parties best.*

Of course it is possible to combine a patent licensing agreement with an ancillary material transfer agreement where a patent protects the licensed technology and, at the same time, the supply of the protected materials to the licensee is secured¹.

3. Cooperation scheme

When defining the subject of a licensing agreement, the nature of the licensed technology needs to be identified. It might be a basic discovery/invention which can potentially be developed into several products for diverse applications, such as a method, or it might be a product with a specific application scope that may be in an early stage of development.

In these cases, when a technology needs further development prior to commercialisation, the contracting parties need to agree on an appropriate cooperation scheme².

4. Scope of the licence

Whenever a biotechnology invention can be used for different applications, e.g. human or veterinary medicine or medicine against different diseases, it is advantageous to pursue different exclusive "field-of-use"-licences. A licensee in the biotechnology sector usually requests exclusive licences in order to gain a competitive edge in return for the generally high financial investment and development risks it bears. Exclusive licensing carries a high risk for the licensor as successful commercialisation depends on the efforts taken by one licensee. By granting several exclusive licences to a number of licensees for different fields of use the risk of successful commercialisation can be minimised while ensuring the competitive advantage of the licensees in their fields of use³.

5. The royalty structure

The royalty scheme can reasonably be structured in compliance with the cooperation scheme and with the subsequent phase of product commercialisation established in the licensing agreement. Apart from an initial licence issue fee, which is often requested for exclusive licences, milestone payments can be provided upon the successful completion of the pre-clinical and subsequent clinical test phases, and an increased milestone payment when the product is officially approved by the competent authorities.

With the sale of the product(s), recurrent royalties are appropriate (e.g. a fixed amount per sold product or percentage rates of the net sale price). They can be modified for subsequent commercialisation stages, in particular for products with expected high and increasing market demand. It is also common practice to combine recurrent royalties with fixed annual minimum royalty rates that are independent of the actual profit. The annual royalty fees can be agreed to be creditable against the actual royalties.

In the event that the licensee is entitled to engage sub-licensees to produce and/or sell the products, the licensor usually also participates, for example by taking a certain percentage of the royalties that the licensee receives from its sub-licensees.

6. Flexibility

Due to the potential of biotechnology described, but also with reference to the risks that will be taken by a licensing relationship, it is important to design a licensing agreement so that it is very flexible, i.e. to include a milestone structure in compliance with the cooperation phases, and to define flexible responses for positive and negative events which may occur in correlation with a milestone.

Modification possibilities should be considered whenever the relationship needs to be adapted due to changed development or business needs as well as contractual termination rights for defined reasons⁴.

1. For further information on material transfer agreements, please refer to [our document](#) on the matter.
2. E.g. if the inventor intended to license a patented broad biotechnological invention to a licensee for application in human medicine for treatment of particular diseases, the contracting parties would need to establish a comprehensive cooperation covering the pre-clinical and several subsequent animal and clinical trial phases up to the registration as a medical product approved by the European Medicine Agency (EMA) or by the U.S. Food and Drug Administration (FDA).
3. Apart from field-of-use licensing, an exclusive licence can be restricted to a geographical area. It also should be noted that within exclusive licensing a sole licence can be agreed upon which entitles the licensor to carry out some or all of the licensed activities in the same geographical area or field of use.
4. For further reading on the scope and content of licensing agreements please consult our document "[Core content of licensing agreements](#)" as well as "[A Guide to Licensing Biotechnology](#)"