

Licensing and negotiations

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March 2022

ISBN 978-87-94331-33-3

A much more detailed description of licensing is provided in the book, *Jakobsen PH. Commercialization of Biotechnology Research. Akademisk forlag 2019, ISBN: 9788750055198*.
A much more detailed description of negotiations is provided in the book, *Jakobsen PH. Negotiations and Decision Making. Akademisk forlag 5 sep 2019, ISBN: 9788750055204*

Collaborations

Collaborations are common with biomedical research in order to strengthen the innovation and commercialisation process.

Collaborations can offer the following advantages:

- Obtaining needed skills or resources more quickly
- Reducing asset commitment and increase flexibility
- Learning from partner
- Sharing costs and risks
- Can build cooperation around a common standard

The motives for biotech and pharmaceutical companies to enter into academic collaborations include:

- Firms increasingly combine internal R&D capacity with external sourcing and networks (“open innovation”)
- Access to know-how and infrastructure
- Recruitment of R&D personnel
- Reducing costs for in-house R&D

There are a number of different tools available to facilitate cooperation between pharma companies and academic institutions, such as:

- License collaborations
- Fellowships
- Innovation awards
- Scientific forums
- Laboratory tools (proteins for experimental use, screenings)
- Mentorships
- InnoCentive – open innovation for problem solutions

Legal documents for collaborations

There are a number of different agreements that may be executed in support of such collaborations. Examples of such agreements in relation to research collaborations are:

- Confidentiality agreements
- Material transfer agreements
- Research collaboration agreements
- Feasibility study agreements

Examples of agreements in relation to commercialisation of research are:

- Confidentiality agreements (CDAs)
- Option Agreements
- License agreements
- Manufacturing and supply agreements
- Contract development agreements
- Sales and Marketing agreements

Licensing

Licensing activities are commonly used to ensure development and commercialisation of research. Licensing is a tool to provide a buyer the necessary rights to use intellectual property for commercialization purposes, with the scope of user rights being defined in the licensing agreement. A license is, according to *Oxford Compact Dictionary*, “a permit from an authority to own or use something, do a particular thing, or carry on a trade”. In a typical licensing agreement, the licensor grants the licensee the right to produce and sell goods, apply a brand name or trademark, or use patented technology owned by the licensor. In exchange, the licensee usually submits to a series of conditions regarding the use of the licensor's property and agrees to make payments such as royalty payments.

A license agreement:

- *Defines the scope of rights being transferred between the parties*
- *Defines the compensation in exchange of these rights*
- *Puts in place a structure for managing the risks that each party takes on in carrying out the agreements.*

Negotiations to secure the deal

The execution of a license agreement is preceded by a – sometimes lengthy – evaluation and negotiation process.

The activities during the negotiation process are:

- Negotiation and execution of a Letter of Intent or a Term Sheet.
- Definition by licensor and licensee of key issues and their negotiation position.
- Joint planning of the negotiation process by the licensor and licensee.
- Negotiation and contract drafting.
- Management approval by both parties and signing of the license agreement.

License agreement

In a license agreement, the licensor grants the licensee the right to exploit specified intellectual property rights, but the licensor retains the ownership of these rights. This construction allows the licensor to receive payments for the license granted over a potentially long period of time (years) and, in many situations, to retain, control and ensure further improvement and development of these intellectual property rights. "Controls" in this context most often means that the licensor either owns the intellectual property rights or that the licensor has the right to grant a license to them, because the licensor itself has a license (with a right to sublicense) under the intellectual property rights.

The License agreement should clearly specify the parties' rights and obligations under the agreement.

License grant and scope of the license

In the license grant section of the license agreement, there should be a statement of the nature of the rights granted to the licensee, for example if the license is exclusive or non-exclusive. If the license is exclusive, the licensor is not allowed to utilize or grant rights to other parties under the same intellectual property rights within the field of the license. A license right to a pharmaceutical drug may often be exclusive. If the license is not restricted to a defined field, the licensee will have the right to utilize the intellectual property rights for all purposes/indications.

If a license is non-exclusive, the licensor will retain the right to utilize the intellectual property rights and to grant licenses to other parties as well. A license right to usage of a technology may often be non-exclusive.

If the utilization rights are limited to certain uses, for example only for research purposes or for manufacturing purposes, it should be stated in the license grant section. The license grant section should also state if the license is granted for a certain geographical territory, or if the license is granted for all countries in the world, instead.

Marketing rights

In a license agreement, the licensor or the licensee may get certain rights to join the commercialisation activities controlled by the other party typically defined as:

Co-marketing rights, where both parties separately market the licensed product under different trademarks,

or

Co-promotion rights, where both parties jointly market a product under the same brand name.

Termination and consequences of termination

Most projects have an implicit risk of failure in the development phase, and a majority of the license agreement that are being executed will therefore end up being terminated at a later stage as no product is being commercialized under the agreement.

There may be a number of reasons why license agreements are terminated. Some are:

- Change in business strategies and goals
- Development failure or serious obstacles in a successful development such as adverse events
- Differences in partner culture and poor integration processes
- Non-compatible objectives
- Poor alliance leadership & ineffective governance structure
- Weak commitment
- Changes in the business environment and overestimated market potential
- A party merges with another company or is acquired by another company.

It should be set forth in the license agreement whether the parties have a right to terminate the agreement. The agreement should also specify what kind of notice is necessary, and whether termination can only take place under certain circumstances or can be done without cause.

The license agreement should also describe the consequences of termination.

Payment Consideration

Payments are typically structured into:

- an upfront fee/technology access fee, to be paid upon signing of the license agreement;
- milestone payments to be paid at certain defined events as the development progresses;
- royalty payments, to be made on sales of a product developed under the license agreement after such a product has been put on the market. It is often seen that the parties also agree to certain milestones relating to the sales of a product on the market reaching certain sales levels.

Negotiations

Negotiations are discussions between people who have different viewpoints and objectives, during which they try to reach an agreement.

There are two types of agreements:

- *Distributive deal making: an agreement in negotiation that allocates a fixed set of resources.*
- *Integrative deal making: An agreement in negotiation that expands the resources to be allocated beyond those resources that would be available if one party took all or two parties compromised (split their differences) on all issues.*

A superior negotiation has the following elements (Lax et.al. 2005): It ensures that the right people have been involved in the right sequence to deal with the right issues that engage the right set of interests at the right table, at the right time under the right expectations and facing the right consequences of walking away if there is no deal.

In order to generate a negotiation strategy, the structure of the upcoming negotiation needs to be analysed. This description should address the following questions (Watkins M. et.al. 2001):

- a) Map the parties in the negotiation: Do they all participate in the negotiation?
- b) What are the problems that need to be resolved?
- c) What are the interests of the parties? How are they aligned or different from the interests of the other parties?
- d) What are the alternatives to a negotiation solution?
- e) Are there potential agreements/solutions which may be acceptable to all parties?

There are three negotiation concepts, which may be useful to understand:

ZOPA

ZOPA is an abbreviation for Zone of Possible Agreement, and ZOPA covers the negotiation spectrum, where all involved parties can accept a negotiation solution like a price of a house acceptable for both the seller and the buyer.

BATNA

BATNA is an abbreviation for *Best Alternative To a Negotiated Agreement*. A BATNA outlines the consequences of not reaching an agreement. A party with a strong BATNA will also have a strong negotiation position and therefore reach better agreements.

Anchoring

Anchoring is a cognitive bias that makes us rely too heavily on the first piece of information offered (the "anchor") when making decisions. Once an anchor is set, there is a bias toward interpreting other information around the anchor. For example, the initial price offered for a used car sets the standard for the rest of the negotiations, so that prices lower than the initial price seem more reasonable even if they are still higher than what the car is really worth. Thus, the use of anchoring may impact the final negotiation outcome.

References

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Edwards M.G. et.al. Value creation and sharing among universities, biotechnology and pharma. Nature Biotechnology, vol 21, 618-624, 2003.

Lax D.A. and Sebenius J.K. 3D negotiation, HBS Press, ISBN 1-59139-799-5, 2006.

Watkins M. and Rosegrant S. Breakthrough International Negotiation. Jossey. Bass. ISBN 0-7879-5743-7, 2001.

When looking for licensing information, the first place to look is a company's website, checking under investor relations, annual reports, press room/releases, financials & product pipeline.

Secondly, look at other internet sites for search of information such as

www.finance.yahoo.com,

<http://www.ft.com/home/europe>,

<http://www.marketwatch.com/>,

www.recap.com

www.pharmaventures.com