All Right

Legal Support for scientists initiating collaboration

Table of Content

Appendixes

Swelife's All Right Legal Support is a set of documents to be used as tools when initiating collaboration. The aim is to stimulate and facilitate discussions and collaboration between potential partners and to act as a gateway to innovation support organisations.

1. Introduction

This document, written on behalf of Swelife, the national Innovation Programme for Life Science, has the overall aim to stimulate collaboration and innovation within Life Sciences. Swelife has identified the initial meeting between potential partners as a bottleneck in this process. The document will make, primarily, researchers more comfortable in initial discussions with potential partners by providing them with a guide to some of the basic legal aspects of initiating interaction with external partners.

N.B. The document should be seen as a legal guideline based on Swedish law, covering some of the issues that require consideration prior to initiation of collaborations within life sciences. Since the process can be complex you are encouraged to contact the Innovation Office at your university to discuss your specific case.

Knowledge on how to identify and correctly handle valuable and confidential information is a key aspect in initial discussions with potential partners. This guide therefore covers the issue of confidentiality and the special conditions researchers face when presenting data in oral or written form. An example on how to present a potential novel drug in a non-confidential manner is described in Appendix I.

An overview of the most important forms of intellectual property rights protection, requirements for protection, costs etc., is found in Appendix II.

The “Due Diligence” process is briefly described in Appendix III, as well as the purpose thereof.

The guide also contains an introduction to common contract types, Appendix IV.

The Non-disclosure Agreement (NDA) and Material Transfer Agreement (MTA) are found among the agreements defined. Template NDAs, both mutual and unilateral, and MTA are attached, Appendix V, VI and VII.

2. Meetings, Presentations and Confidential Information

As mentioned above in the introduction, identifying, and knowledge of how to treat, confidential information is key in initial meetings with potential partners.

2.1 Meetings

The process of developing a research finding to patient benefit is often expensive, and frequently requires additional skills to those the researcher possesses. An academic partner or a business partner, such as an investor, venture capitalist or company established in the relevant field, may be necessary to bring the innovation to the market for instance by obtaining the capital needed to apply for patents and developing the innovation into a finished product. All collaborations start with discussions/meetings and sharing of information.

2.1.1 Initial meeting(s) – no confidential information disclosed

In order to gain attention from potential partners, the initial non-confidential presentation of your idea/research finding is crucial. As a scientist, you need to clearly tell your story in a way that is convincing and provide the information potential partners will be interested in and that will enable them to determine if they want to learn more. The first thing to communicate is "*What is special about your approach?*" If the uniqueness of your approach is not clearly conveyed from the start, a potential partner might never appreciate the benefit of your proposition and lose interest in continuing discussions with you.

At initial meetings, information should thus create interest for your idea/research result, however without disclosing actual information regarding your invention or otherwise regarding your business secrets. If presenting hard data, include only what is already in the public domain. Exclude information concerning chemical structures, manufacturing processes etc., unless they are already in the public domain. Exclude anything that may form the basis of a future patent filing.

An example on how to present a potential novel anti-hyperglycemic drug in a non-confidential manner is described in Appendix I.

It is important to keep in mind that disclosure of confidential information may have the consequence such information becoming public and thereby losing valuable business secrets and the opportunity to obtain intellectual property rights.

A tool that can be used for the development, assessment and presentation of ideas is the so-called NABC method (Needs, Approach, Benefits and Competition). Contact the Innovation Office at your university if you are interested in performing a NABC analysis of your idea.

2.1.2 Meetings which might involve the sharing of confidential information

After initial meetings with possible business partners, meetings may take place where confidential information will be provided to such possible business partners. In this connection, the following should be observed.

Before a formal collaboration has been established, the researcher and potential partner will have, at least to some degree, conflicting interests. The researcher will want to share as little information as possible with as strong limitations on the use of the information as possible, while the possible partner will want to know as much as possible without obligations regarding the received information. The most important things to think about in such situations are:

i. Limit the information given: It is essential to consider and decide before a meeting exactly what information that should be disclosed to the possible partners, and how. As a general rule, do not share know-how, technical information concerning an idea/research finding or other confidential information unless it is necessary. Regarding computer programs, do not show any code or the program architecture. Regarding technology, it is usually sufficient to describe the problem that is solved, and/or the advantages with the idea/research finding. To the extent information is disclosed, it may also be preferable to limit the amount of information provided on paper or electronic form.

ii. Other limitations: It is a good idea to ask who will represent your potential partner at a meeting, and what background they have. If the potential partner wish to bring

along people with too much of a technical background, especially if they are experts in the same field as the presenting researcher(s), it could be preferable to suggest meeting other representatives instead. It is perfectly valid to tell a potential partner that you do not want people with a certain background present at the initial meetings due to the sensitive nature of the information that will be shared.

iii. Non-disclosure agreements (NDAs): An NDA is a contract stipulating how the receiving party is allowed to handle confidential information. The concept is further discussed below. Professional investors are familiar with, and will accept an NDA. No meetings where confidential information will be, or is likely to be, disclosed should take place without the counterpart first signing an NDA. As already mentioned, template NDAs (Mutual and Unilateral) are attached, Appendix V and VI.

2.2 Presentations and publications

It is in the nature of research that researchers want to share research results in public presentations and written publications.

What is shared during a public presentation or in a written publication have in fact been made public.

If shared information in a presentation or publication contains technical details of a research result to which patent application has not yet been submitted, the possibility to apply for a patent may be lost as a result of the novelty requirement for patents. Similarly, it should be kept in mind that such information that could be protected as confidential know-how, will be free for anyone to use if made public.

There are other intellectual property rights that are not as sensitive to being made public. If a product prototype exists and the visual design of it is revealed, the owner of the design can generally still apply for registered protection for up to a year after the disclosure. In the meantime the design may still enjoy unregistered design protection, as well as copyright protection. The Innovation Offices at the universities can provide further information concerning this.

A few things to consider regarding content and timing before having a public presentation or publishing a written paper:

- Does a Material Transfer Agreement (MTA, see Appendix VII) exist that limit the possibility to publish research results? Is consent by the university or other third party required/agreed upon before any presentation or publication?
- What is to be published?
- Is there a potential patentable invention?
- Is valuable know-how revealed in the presentation or publication?
- Can the presentation or publication wait until a patent application has been filed?
- Can the presentation or publication be adapted so the technical solution or know-how is not disclosed?

The matter of know-how and trade secrets is further treated in Appendix II – Trade Secrets.

2.3 Handling confidential information in general

Sound routines concerning how to treat confidential information are a prerequisite for stimulating collaboration and innovation. A first step is to continuously identify information that can constitute or become valuable assets. The guide to the different forms of IPR's in Appendix IV can be of some assistance in performing this task.

Other suggested actions are:

- If there is more than one scientist involved in a project; discuss and decide together the routines to apply,
    - Decide who should be allowed to access and use the confidential information. It is not always necessary to grant full access to all employees; on the contrary, confidential information should, as a rule, be handled strictly on a need-to-know basis,
    - Use NDAs (but even with NDAs in place, be restrictive), and
    - Have routines in place that will limit employees' or third parties' use of confidential information. Examples of this can be to prohibit employees from copying confidential information, bringing confidential information from work, etc.

- Analyse what information that might be sensitive and deemed confidential. This should be done continuously. Sort out information that can be shared without risk of losing opportunities for protection,
- Do not spread information and store information safely. If stored on a computer, encryption can be a good idea. If in paper (or other) form; information should if possible be locked up,
- Be aware that using email at public institutions (such as universities) may impose risks that information enclosed in such emails may become public information under Swedish legislation.

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