

Standard Operating Procedures for IP Contracts and Guiding material

Created by Marius Kuningas

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1. Purpose

The Standard Operating Procedures for Contracts (SOPs) provides administrative support and assistance to the ALLIANCE members in intellectual property (IP) related contract drafting and to ensure the proper protection of the ALLIANCE's and its members interests.

2. Prerequisites for IP contract drafting

Before undertaking the challenging task of drafting an IP contract and during the usual preliminary negotiations leading to a business partnership, it is important to consider several questions, which will determine the specific drafting of the clauses and, in general, how the business under the contract is to be conducted.

2.1. Definition of a Contract

A Contract is an agreement, based on consensus between legal subjects with contractual capacity, which is legal, physically possible and complies with the prescribed formalities and which is reached with the intention of creating a legal obligation with resultant rights and duties.

2.2. Strategy of the parties

The parties must inform each other about the aims sought under their collaboration to anticipate any applicable laws and therefore, whether the business sought is feasible from a legal perspective, as well as to foresee any potential IP issues resulting from such collaboration.

2.3. Applicable laws and types of IP

It is essential that the parties know the mandatory rules that apply to their contractual relationship, and the types of IP that will be included in the agreement, in order to assist them in understanding the type of contractual relationship allowed and the impact that will have on the project. For instance, in some jurisdictions, trademarks may only be legally transferred or licensed when accompanied by the associated goodwill and, under German, Croatian, Hungarian, Czech, Slovakian and Austrian laws, assignments of copyright are not allowed.

2.4. Freedom-to-operate

Prior to carrying out any business project, the parties must establish whether they will actually be able to exploit any results derived from such project – e.g. through a freedom-to-operate (FTO) search – to determine whether a product's commercialisation would infringe third parties' rights. FTOs are often performed in the context of IP due diligence processes.

2.5. IP Protection

In a business collaboration, it is usually advised that each party protects their own background IP by any applicable means, such as the registration of IPRs or the collection of evidence where registration is not possible or not mandatory, such as with copyrights. This will avoid potential

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conflicts as to which party owns what and which rights of use each party enjoys regarding their own IP.

2.6. IP due diligence

The parties should gather and perform an in-depth analysis of all their IP-related information and documentation, in order to assess the risks potentially involved in a business collaboration or a transaction.

2.7. Confidentiality

Contractual negotiations necessarily imply the disclosure of information by the parties. The information is often sensitive and its disclosure to third parties may damage the parties' respective and potential future business. Therefore, and to avoid any issues deriving from such disclosure, it is recommended to start by concluding a non-disclosure agreement (NDA) or include a confidentiality clause in the main agreement.

2.8. Material transfer agreement

In the area of research, it is common that the parties exchange tangible materials, such as biological materials, chemical compounds, prototypes or even software. To protect such materials and regulate their use by the recipient in these pre-contractual stages, concluding a material transfer agreement (MTA) is advised.

2.9. Competition laws

Business practices can sometimes be in conflict with the prohibitions contained in national and EU competition laws. When it comes to IP contracts, companies often enter into concrete arrangements, which may be considered as anticompetitive in accordance with such laws. Before including this type of arrangement in a contract, the parties should make sure whether such an arrangement is in compliance with competition laws. Lack of compliance with competition laws can entail significant fines and/or court proceedings.

2.10. Recording of the agreement

When it comes to IP contracts, such as licence agreements, some national and European laws may require the recording of the agreement within the registers of their intellectual property offices in order for it to be legally valid and/or enforceable. Therefore, when applicable, it is advisable to include a clause regarding the obligation to register the agreement and to pay any relevant fees.

2.11. Special employees

The parties should identify those employees with a particular status. For example, in research collaboration with university professors, it must be born in mind that some university professors enjoy the so-called "professor's privilege", under which university researchers own any IP they create. This, as well as many other issues in the field of employment law, is a matter of national law, which should be verified at the earliest stage possible in order to avoid any conflicts.

2.12. Interim agreements, feasibility agreements and prototype agreements

These are short-term agreements concluded (not necessarily) as a preliminary step in order to anticipate the success or viability of a licence agreement.

3. Special considerations related to different agreements

3.1. Licensing agreement

An IP licence agreement is a contract by which the owner of the IP (licensor) allows a third party (licensee) to exploit certain IP assets within the limits set out by the provisions of the contract. In exchange of the rights granted under the contract, the licensee usually pays a price, which may be a lump sum, royalties and/or other types of payment.

An IP licence is usually comparable to a rental; it does not imply the permanent transfer of the IP in question, which would be an assignment.

There are different types of IP licences, the choice of which will usually depend on the licensor's business strategy, the target market conditions and the capabilities of the licensee:

Exclusive licence: the licensor can only license the IP to one licensee.

- **Exclusive:** it is the licence with the broadest scope. The licensor retains ownership but grants the licensee the right to use the licensed IP on an exclusive basis (i.e. the owner of the IP is not allowed to use the IP either). An exclusive licensee is often entitled to sue for infringement (either alone or jointly with the licensor, depending on the applicable laws and contract terms).
- **Sole:** the licence is only granted to one licensee and excludes the licensor from granting licences to any other person, while the licensor retains the right to use the licensed IP. In general, national laws only refer to exclusive or non-exclusive licences, therefore licence agreements should always clearly define what is intended by the parties.

Non-exclusive licence: the licensor can grant licences to as many licensees as desired, while retaining the right to use the licensed IP. Usually, and subject to applicable laws and contract terms, nonexclusive licensees are not entitled to sue for infringement, as it is usually the licensor who must bring the action.

Cross-licence: the parties grant each other licences to their respective IP. For each party the licences are (part of) the compensation for the licences which each party grants.

Sublicence: licence granted by a licensee (sublicensor) to a third party (sublicensee), which extends part or all of the rights enjoyed by the licensee under the licence agreement to the sublicensee. The right to grant a sublicense is usually not implicit, and therefore, for it to apply, it must be included in the licence agreement, which usually expresses whether the licensor's prior written approval is required for:

- The granting of any sublicense.

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- The choice of sublicensee (e.g. companies pre-approved by the licensor).
- The conditions upon which the terms of the sublicense should accord with those of the licence agreement.

3.2. R&D agreements

There are two main types of research and development (R&D) agreements: (i) where a company outsources R&D activities to a research institution or university under a research contract (contract research) or (ii) where companies enter into research collaborations with other companies, including competitors, to carry out R&D activities (collaborative research).

When concluding the R&D agreement, it is important to pay attention to the following:

Payment: it is common for the payment to be divided into instalments to be paid as the different phases of the project take place.

IP management: an IP management strategy covering the following issues should be established – (i) IP ownership and access rights; (ii) IPRs registration protocol; (iii) Exploitation strategy; (iv) IP management in case of termination of the agreement.

Note that background IP remains the property of the party that generated it. It is possible to create a pool of IP rights for the party's use for the duration and purpose of the research activities. In contract research the project results are usually owned by the company whereas in collaborative research the results usually stay with the party that generated them. Regarding inventions, co-ownership of results may be combined with a field-of-use clause, specifying and restricting how the parties may apply and use the research results.

Access rights refer to rights granted by the parties to each other, as opposed to licences to third parties. They should determine which parties can use which pieces of results/background, for research purposes and/or for exploitation purposes, and on what conditions.

Exclusivity: in contract research, the parties may want to impose exclusivity clauses among themselves, for example by undertaking not to enter into any kind of cooperation, including providing advice or consulting, in the project's area with third parties. This reinforces confidentiality and decreases the chances that the parties' competitors embark on similar projects, which may constitute a threat to the business success of the project's results.

Publication: some national laws, depending on the type of funding and project, require the publication and dissemination of research results. Therefore, the parties need to be well aware of any rules in this respect before and during the contract drafting.