INNOVAUD - CONNECT

In- and Out-licensing in Life Sciences

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My background

- Admitted to the Swiss bar in Zurich

- Employments at a renowned business law firm based in Zurich and more recently at Swissmedic

- Since January 2014, at **id est avocats** based in Lausanne, specialized in Intellectual Property, Advanced Technologies and Corporate matters
Today’s objectives

- Practical and relevant advice for your business
- Facilitate communication with your partners and counsels in IP licensing matters
- No replacement for circumstantial advice in a specific case

Intellectual Property (IP) licensing, in particular in Life Sciences, is a complex and extensive matter with potential implications in other legal areas such as anti-trust law, tax law, etc. which are not covered by this presentation.
Overview

I. Introduction

II. Main elements of a license agreement

III. Common pitfalls

IV. Summary
I. INTRODUCTION
IP includes patents, copyright, trademarks, designs, trade secrets and know-how

A license is a contract by which the licensor grants the licensee, under certain conditions, certain rights under its IP

No transfer of ownership

Ongoing contractual relationship
In a Life Sciences company, IP is often the most important asset.

Development and/or exploitation of such IP are tied to important costs and high risks over a long period of time.

It is impossible to anticipate all prospective developments:
- Technological / scientific issues
- Regulatory issues
- Competitors

In order to be sustainable, license agreements need to be flexible, yet reliable!
Licensing considerations

Considerations for out-licensing
- Increase revenue
- Secure funding
- Win market share
- Externalize risk (split-off)
- Retain control over out-licensed IP

Considerations for in-licensing
- Gain (faster) access to technology, know-how, etc.
- Minimize risk
- Dispute resolution or prevention
The grant of a license is often the central element of an extensive collaboration agreement
- Co-marketing agreements
- Co-development agreements
- Joint Ventures

This presentation will focus on licensing and will not go into detail regarding other aspects of such collaboration agreements.
II. MAIN ELEMENTS OF A LICENSE AGREEMENT
General terms

- Recitals
- Definitions
- Hierarchy
- Assignment
- Non-competition / non-solicitation
- Liability and indemnification
- Amendments
- Dispute resolution, jurisdiction and applicable law
- Term and termination
Precise description of the licensed IP
- Patent, trademark, design
- Copyright
- Trade secrets, know-how

Special attention is required if “materials” are exchanged, as IP is often embodied in tangible property (dual nature)

Ideally the description given in the agreement should allow for evaluation of the subject matter from an outside perspective (i.e. judge/arbitrator)
Scope

- **Territory**
  - Worldwide / specific countries

- **Exclusivity**
  - Exclusive / non-exclusive
  - Sole

- **Beneficiaries**
  - Affiliates
  - Sub-licensing

- **Field of use**
  - Diagnostics / treatment (of a certain disease)
  - Human applications / veterinarian applications
Representations and warranties

- Warranty that the licensor has all right and title to grant the license

- Warranty that the licensee’s use of the licensed IP, in accordance with the terms of the license agreement, will not infringe upon any third party rights

- Indemnification
Accessory obligations

Protection of the licensed IP

- Non-disclosure obligations
- Filing and maintenance of registrations

Defense

- In case of any infringement of licensed IP by third parties
- In case of any attack on licensed IP (e.g. for patent invalidity or infringement of third party rights)
No transfer of the licensed IP

Derivatives = IP developed by the licensee based on the licensed IP

- Joint ownership
- “Grant-back” assignment to the licensor (free / against payment)
- “Grant-back” license (exclusive / non-exclusive / free / fee bearing)
- First option or right of first refusal on a license
Financial terms

- **Upfront payments**
  - Provide certainty and fast liquidity for the licensor but do not allow to take into account unpredictable prospective events

- **Milestone payments**
  - Allow to condition payment of fees upon uncertain prospective events
  - In the Life Sciences Sector the completion of clinical trials and authority approvals provide for practical milestones

- **Royalties**
  - Allow for a maximum adjustment of payments to the actual value of the licensed IP but are also the source of a lot of disputes
III. Common Pitfalls
Problem

- The agreement lacks a clear structure; (sometimes contradicting) provisions regarding the scope of the license are found in the chapters regarding payments, etc.

Recommendations

- In order to be clear and consistent, the agreement should have a proper structure
- As a first step of drafting, the structure of the contemplated agreement should be laid out
Problem
Unclear definitions and inconsistent use of defined terms create ambiguity when it comes to interpretation of the agreement.

Recommendations
- It is important to do define terms with upmost care, as minor variance may have major impact.
- If a term is defined, it should be used consistently.
Problem

Complex negotiations and long-term business relationships produce a multitude of documents (offer, letter of intent, framework agreement, statements of work, addenda, etc.)

Recommendations

A hierarchy clause should establish which document shall prevail in case of contradiction

Formalities of how to amend documents should be defined (e.g. only by a written instrument duly executed by both parties)
Problem

- A clear definition of the subject matter is crucial, yet at times very technical and hard to put into words
- Communication gap between science and business

Recommendations

- Business departments and external counsels should communicate with scientists/engineers in order to understand scientific/technical aspects
- It may be appropriate to define complex or voluminous subject matter (e.g. a formula, molecule or code) in a dedicated annex
Problem

- Tangible material (in particular biological material) is transferred without a proper agreement regarding embodied IP
- Biological material is also a tool for its own reproduction and creation of derivatives

Recommendations

- The provider of tangible material should be aware that such material often embodies IP and that this should be properly addressed before any transfer is made
- IP rights in progeny and derivatives should be addressed in case of biological material
Problem
- Possible enhancements and developments of the licensed IP made by the licensor after the conclusion of the agreement are not addressed in the agreement.

Recommendations
- It should be clearly stated whether prospective enhancements and developments are covered by the license, and under which conditions (e.g. adjustment of financial terms).
- If this is the case, a clear distinction between enhancements to existing IP and new IP (not covered) should be provided.
Scope

**Problem**
- The field of application is defined too extensively (or too narrowly)

**Recommendations**
- The parties should carefully consider the objective of a contemplated license and consider which rights they give up (licensor) respectively need (licensee)
- Future plans and potential of the licensed IP should be taken into account as far as possible
Problem
- The field of application is defined ambiguously

Recommendation
- The parties should prevent overlap between a licensed field of use and a non-licensed field of use (e.g. diagnostics and treatment might sometimes overlap) to make sure to license allows
  - the licensee to use the licensed IP as intended
  - the licensor to restrict such use as intended
**Problem**

- The licensee relies on affiliates and external partners and this is not addressed in the license agreement.

**Recommendations**

- The licensee should carefully consider who should benefit from the contemplated license.
- It should be clearly stated whether affiliates benefit from the license and affiliates should be clearly defined or identified.
- It should be clearly stated whether and under which conditions the licensee may grant sub-licenses.
**Problem**

- The licensee creates derivatives based on the licensed IP and the license agreement does not (sufficiently) address ownership of such derivatives.

**Recommendations**

- If it is intended that the licensee creates derivatives, the parties should take this into account in the negotiations and allocate IP ownership of such derivatives.
- This should also be addressed if the licensee is not allowed to, but is technically in a position, to create derivatives.
Representation and warranties

Problem

- The licensee relies on representations and warranties regarding the licensor’s right and title in the licensed IP and non-infringement of third party rights.

Recommendation

- IP rights are often registered and the licensee should in this case not rely solely on the licensor’s representations and warranties but check the registers.
Problem

Protection of the licensed IP depends on the filing and maintenance of registrations in different jurisdictions.

Recommendation

The agreement should clearly state which party is responsible for the filing and maintenance of registrations, including allocation of registration fees.
Problem
- The licensed IP is infringed by a third party or a third party challenges the licensed IP in court (e.g. patent invalidity claim)

Recommendations
- The agreement should allocate control over proceedings and related costs
- The agreement should provide for an obligation of the parties to support each other in such proceedings
Problem

- The agreement provides for milestone payments but the parties do not agree whether a certain milestone was achieved or whether certain milestones are achievable.

Recommendations

- The agreement should clearly identify milestones.
- The licensee should be obliged to undertake all actions, and with all due care, in order to achieve milestones and to report to the licensor regarding such undertakings.
- In case milestones are missed, the agreement should provide an a right for the licensor to terminate the agreement.
Financial terms

Problem

The agreement provides for royalty payments but the payments received by the licensor remain below expectations.

Recommendations

The agreement should provide for an obligation of the licensee to keep records and to report them to the licensor.

The agreement should provide for a right of the licensor to mandate an auditor to audit the licensee’s books (shift of audit costs to the licensee in case of significant underpayment).

The licensor should make use of his right to audit!
Problem

Royalties are calculated on the licensee’s sales of the licensed product; for the development of the licensed product or its exploitation in a certain market, the licensee needs to obtain further royalty bearing licenses (royalty stacking).

Recommendation

The licensee should try to impose a ceiling on total royalties to be paid, on the other hand the licensor should in this case try to impose a floor to minimum royalties on his end.
Problem

- A competitor of the licensor acquires a majority interest in the licensee

Recommendations

- The agreement should provide a termination right for the licensor in case of “Change of control” and an obligation for the licensee to notify the licensor of any such event
- The term “Change of control” should be clearly defined
IV. SUMMARY
Key reflections for licensing

What is the objective of the contemplated licensing agreement?

What shall be the licensed IP?
Which rights shall be granted to the licensee?
How shall the licensor be remunerated?
Shall there be other rights and obligations?
What shall be the term of the agreement / the license?
What might be the reasons to terminate the agreement?
What shall happen when the agreement expires or is terminated?