Licensing Playbook

The Israel Innovation Authority
8400 – The Health Network
ITTN – Israel Technology Transfer Network

רשות החדשנות
Israel Innovation Authority

8400
THE HEALTH NETWORK

iTTN
Israel Tech Transfer Network

CREDITS & CONTRIBUTORS

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1.INTRO

INTRO

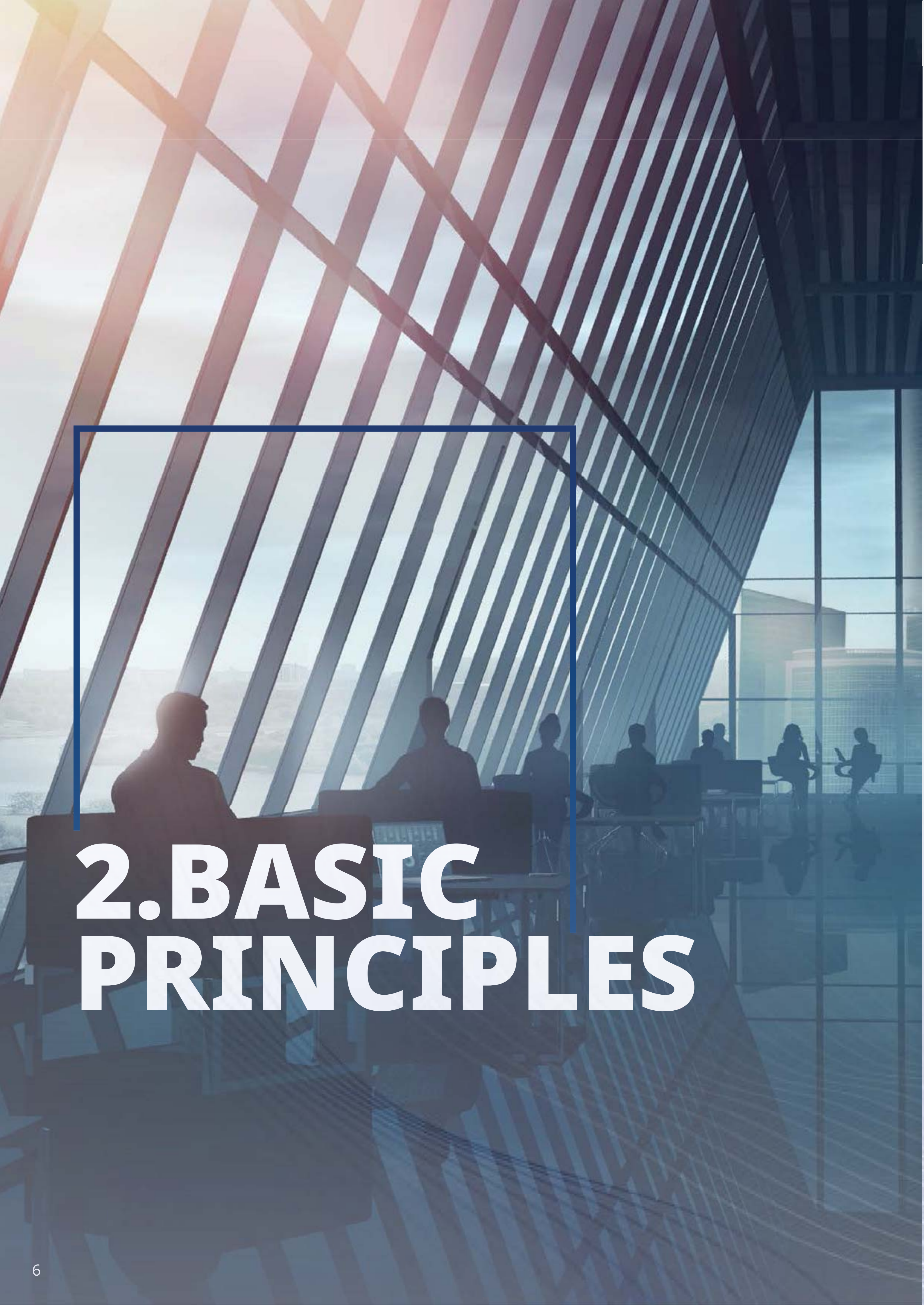
This playbook is intended to serve as a tool for entrepreneurs and other potential licensees to have a better understanding of the basic concepts of licensing transactions. It is geared towards entrepreneurs, start-up companies and other entities that strive to license-in and to continue the development and commercial exploitation of intellectual property originating with third parties, such as, universities and hospitals (collectively "Research Institutions").

The terms and conditions of a License Agreement can have far reaching ramifications both on the chances of technologies to reach the market, and on the commercial success of a licensing entity, particularly start-ups.

Typical scenarios, legal principles and legislation described or mentioned below are with reference solely to the Israeli ecosystem and Israeli law. While many of the commercial principles may be similar, agreements with international companies may be governed by foreign law.

This playbook does not constitute a comprehensive guide and should not be relied upon in negotiating or drafting term sheets or agreements. Licensing agreements are complex and specific legal and commercial advice should be sought from experienced professionals.

Moreover, for clarity, all information appearing in this playbook is of an advisory nature and should not be seen as constituting professional advice. Reliance upon the contents of this playbook, in whole or in part, is at the sole responsibility of the reader. The Innovation Authority and ITTN will not bear any responsibility for any direct or indirect consequence and/or damage and/or expense caused to or sustained by a reader as a result of that stated in this playbook.



2.BASIC PRINCIPLES

Basic Principles

What is a licensing transaction?

A licensing transaction is a transaction whereby a “Licensor”, who is a party that owns or controls intellectual property (“IP”), grants permission to another party (the “Licensee”) to exploit the relevant patents and/or know-how (the “Licensed Technology”), against payment of consideration (the types of which are detailed below) (a “License”).

Prior to entering a licensing transaction, the parties will typically start their discourse and exchange information under the terms and conditions of a confidentiality agreement (known as a non-disclosure agreement or a confidential disclosure agreement – NDA or CDA). If interest is expressed in initiating negotiations, the parties will sometimes sign a Term Sheet, the aim of which is to establish an agreed roadmap towards the negotiation of a license agreement (more on term sheets below). In other instances, the parties prefer to proceed directly to a full binding agreement, without it being preceded by a term sheet.

Licensing transactions are usually governed by a definitive agreement titled “Research and License Agreement” or “License Agreement” (in each case, referred to below as a “License Agreement”). A Research and License Agreement, which is more typically signed with Research Institutions or their TTOs, provides for sponsored research to be carried out at the Research Institution by the principal investigator who invented the IP, and his/her team. We therefore customarily differentiate between 2 types of agreement – License Agreements that only include the grant of a License to the Licensed Technology and Research, and License Agreements that also cover the Licensee's ongoing research funding at the Research Institution.

Who are the parties to a License Agreement?

The parties to a License Agreement are (i) one or more Licensors who own or control the Licensed Technology and are interested in granting rights to the Licensee to exploit the Licensed Technology in return for compensation and (ii) the Licensee, who wishes to attain such rights, to continue the development, and commercially exploit the Licensed Technology.

It is important to clearly identify all parties by indicating their full legal names, type of entities and place of registration, addresses and contacts for notifications.

Research institutions are typically represented in licensing transactions by their authorized technology transfer offices ("TTOs"). This terminology, which originates in the USA, infers that TTOs are organized as internal departments within the Research Institutions themselves, which is sometimes the case in Israel. In other cases (and more prevalently), TTOs are organized by Research Institutions as wholly owned, independent legal for-profit corporate entities, who are authorized to commercialize IP originating at the Research Institution.

Inventions are sometimes co-owned by more than one Research Institution (or their TTOs). In such cases, the internal relationship between the two owners is governed by what is commonly titled an "Inter-Institutional Agreement" which determines the scope of authority afforded to the Research Institution leading the negotiations. The "lead" institution usually has authority to represent both Research Institutions (and their TTOs) at the negotiation stage. Both Research Institutions (or TTO) or the lead Research Institution (or its TTO) will sign term sheets and/or License Agreement on behalf of the other Research Institution, all in accordance with the terms of the Inter-Institutional Agreement.

The division of compensation between two or more Research Institutions (or their TTOs) that together license joint inventions, is determined by the relevant Inter-Institutional Agreement.

Term Sheets versus License Agreements

In some cases, potential Licensees sign what is usually captioned as a "term sheet", "letter of intent" or "memorandum of understanding" with Licensors, which summarize the key elements of a future License Agreement (collectively: "Term Sheets"). These material terms include many of the issues that are summarized in this playbook.

In the world of startups, the intended Licensee can be a company still in formation. Consequently, if the Licensee is still a company in formation, Term Sheets are often entered into by one or more entrepreneurs (an "Entrepreneur") acting in the name of the Licensee.

A Term Sheet will usually afford the Entrepreneur, or the fledgling company designated as the future Licensee a fixed period of time to raise seed funding to demonstrate that the Licensee can, at least initially, carry out its contractual undertakings under the License Agreement (the "Pre-Conditions"). Such undertakings may also include funding-sponsored research over a specified period of time.

Beyond the underlying obligation to act in good faith in the negotiation of the License Agreement, which is a requirement under general principles of Israeli law, the provisions of the Term Sheet will usually be non-binding, except for the following:

- What is referred to as a "no-shop" period (see below); and
- Confidentiality.

During a "no-shop period" (if there is one), the Licensor will be obligated to refrain from soliciting offers for and/or entering into agreements with third parties in relation to the IP to be subject to the License. Moreover, some Licensors may demand that the potential licensee bear ongoing patent expenses during the "no-shop" period.

The Term Sheet may provide that during the "no-shop period" (if there is one) or any extended negotiation period, the following interactions may be conducted: (i) the potential Licensee may evaluate the Licensed Technology to be licensed; (ii) the potential Licensee shall make efforts to satisfy the Pre-Conditions; and/or (iii) the parties shall negotiate in good faith to finalize the terms of the definitive License Agreement.

Should the Entrepreneur and/or the Licensee succeed in meeting the Pre-Conditions and to negotiate, finalize and execute the definitive License Agreement with the Licensor within the agreed time frame, the Term Sheet will be replaced by the License Agreement, which will then govern the relationship between the parties in all matters pertaining to the License.

What is the role of the inventors?

The individuals who conceived of and/or developed the Licensed Technology (the "Inventors") are named on patent applications, but do not typically own the underlying IP themselves. In the case of Research Institutions, the Inventors are researchers, physicians or other collaborators who are employees or consultants of the Research Institution (collectively: "Researchers").

Inventors, who usually conceive of the inventions during the course of, or due to their employment, assign ownership rights to their employers or their TTO, so that they themselves do not have the right to commercially exploit the Licensed Technology. In cases where the Inventor is an employee, the Inventor will not be a party to the License Agreement between the Licensor and the Licensee and will not bear any personal liability. If however, the Licensor is a Research Institution (or its TTO), the Researchers – although not themselves signatories to the License Agreement – are usually required, to confirm and declare, by signing an attestation that appears at the bottom of the License Agreement, that they are familiar with the terms and conditions of the License Agreement and that they agree to abide by its terms. This is important primarily in the context of sponsored research, confidentiality and publications.

Researchers may be direct parties to Sponsored Research Agreements and/or Consultancy Agreements.

Sponsored Research/ Consultancy Services

Sponsored Research is carried out on the premises of the Research Institution and with the use of its infrastructure and equipment.

The parties to a Sponsored Research Agreement will be the TTOs (and in some cases, the Research Institution directly), and the Researcher(s).

Consultancy services usually provide for the Researcher's high-level input being provided to the Licensee in connection with the Licensed Technology, and do not involve the use of the Research Institution's premises or resources.

The parties to a Consultancy Agreement between the Licensee and a Researcher may or may not include the Research Institution or TTO as a party to the Consultancy Agreement, according to the internal policies of the Research Institution. Regardless, any such Consultancy Agreements must be entered into in compliance with the specific IP rules of the Research Institution employing the Researcher and may be subject to the prior approval of such a Research Institution, even in the case of a Consultancy Agreement to which the Research Institution is not a party.

The compensation of Researchers whose inventions are commercialized through TTOs is governed by the individual management policies and/or IP rules of each Research Institution.

Research Institutions are adverse towards the restriction of academic freedom, and License Agreements with Research Institutions do not usually contain non-competition clauses on the part of a Licensor. In certain instances, however, this issue may be addressed in stand-alone consultancy agreements with Researchers that, as noted above, are not always subject to approval by their employers.

Additional terms and conditions including payments, ownership of data and patents resulting from Sponsored Research or Consultancy Services and the roles of the Researchers should be negotiated between the parties and reflected in the relevant documents.

What is the source of the Licensed Technology/ third party rights?

A licensing transaction is entered into with a Licensor who owns or controls the Licensed Technology which is of interest to the Licensee.

"Owns or Controls" in this context: means that the Licensor is the owner of the technology or that the Licensed Technology is in the Licensor's rightful possession, and that the Licensor has the right to grant the License to the Licensee without violating the terms of any agreement between the Licensor and the owner of the Licensed Technology, or any other third party.

It should be also noted that IP may be owned by one or more Licensors, in which case it is recommended to familiarize yourself with the underlying agreements between them which, in the case of Research Institutions, are the relevant Inter-Institutional Agreements.

Furthermore, even in the case of a Researcher's clear affiliation or ownership trail leading directly to his/her employer, this information is not sufficient.

First, it is important to ascertain whether the Licensed Technology has been previously licensed to a third party. As will be explained below, Licensors contractually demand claw backs of Licensed Technology if a Licensee terminates a License Agreement for reasons of convenience, fails to meet stipulated development or other milestones or otherwise fails to fulfil its contractual undertakings, in which case a License Agreement can be terminated by the Licensor. The common consequences of termination of the License are that the Licensee must cease utilizing the Licensed Technology, and that the Licensed Technology together with developments carried out by the Licensee, are returned to the Licensor. Thus, at times, IP developed by a prior-Licensee can be part of the package of technology offered under a License.

Moreover, such IP may have been developed with financial support from granting authorities, such as the Israeli Innovation Authority (the "IIA") or other third parties. See the next chapter ("Grants") for more information on this subject.

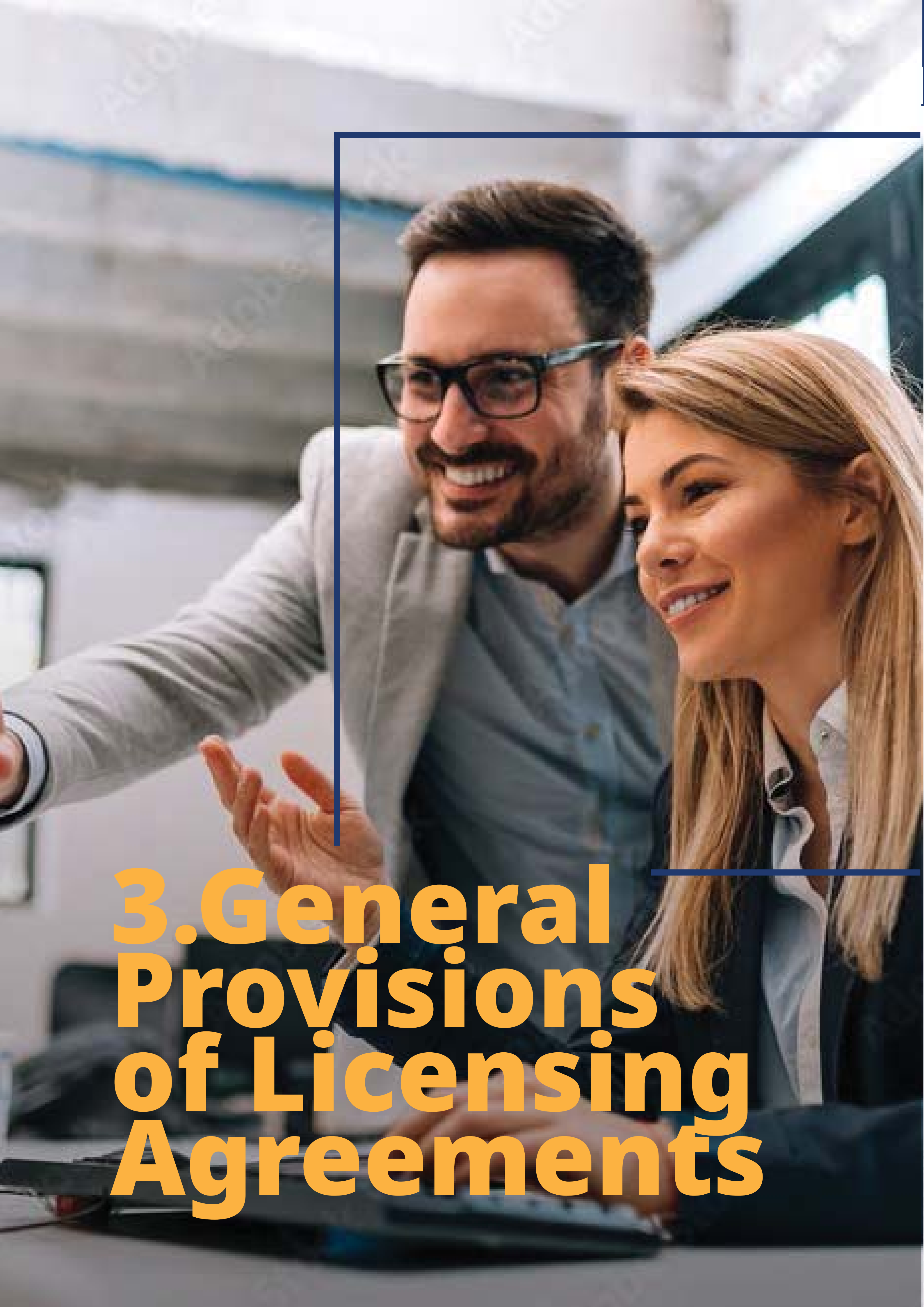
Grants

IP owned or controlled by a Licensor may have been developed with the utilization of research grants from various sources and of different natures. The IIA offers a variety of funding tracks, both to Israeli companies and to Israeli Research Institutions. Israeli entities and Researchers also obtain funding from various Israeli government ministries, as well as through participation in international consortiums such as Horizon Europe (formerly Horizon 2020), the Israel-United States bi-lateral organization known as the "BIRD Foundation" or from charitable organizations.

While most grantors do not demand any rights in the resulting IP, some grants come with "strings attached".

For example, the IIA is focused on incentives to enable growth of manufacturing infrastructure in Israel. Thus, IP developed with support from the IIA is subject to the provisions of the Law for the Encouragement of Research, Development and Technological Innovation in Industry–1984 as amended (the "R&D Law"), and to the provisions of the relevant benefit track. These include, among others, restrictions on transferability of the resulting IP to third parties both inside and outside Israel, as well as manufacturing of the resultant products outside Israel. Moreover, certain grant tracks require payment of royalties to the IIA on sales of the products developed with the support of such grants, up to the amount of the grant plus interest.

Thus, licensing-in of Licensed Technology which has been developed by parties other than that which owns or controls the Licensed Technology, and/or with funding obtained from third parties other than the Licensor, may have various ramifications which should be carefully scrutinized by the Licensee prior to the execution of a License Agreement.



3.General Provisions of Licensing Agreements

General Provisions of Licensing Agreements

Recitals and Definitions

License Agreements often open with recitals that generally identify and describe the source of the Licensed Technology and the framework of the licensing transaction.

Moreover, when the Licensor is a TTO, the recitals often serve to confirm the relationship between the TTO and the Research Institution, and the authority of the TTO to commercialize the Licensed Technology, to enter into the License Agreement, and to grant the rights to the Licensee thereunder.

The "Definitions" section of a License Agreement

The "Definitions" section of a License Agreement contains definitions of multiple words and phrases which are used throughout the License Agreement, and which are crucial in reflecting the parties' intent. After the License Agreement is signed, these definitions will affect the interpretation of numerous provisions of the License Agreement. Special attention should be directed towards the formulation of the definitions of terms such as "Affiliates", "Licensed Patents", "Licensed Know-How", "Licensed Materials", "Field of Use", "Licensed Products", "Net Sales", "Royalty Term", "Sublicensee", "Sublicense Receipts" and "Valid Claims", among others. These definitions should be used consistently throughout the License Agreement.

More detail on these concepts appears below.

Subject Matter of the License

Licensed Technology can take the form of patents (including patent applications), know-how (including materials), copyrights and trademarks or any specific item or combination of the foregoing. Agreements which grant access rights to data take a similar form.

Licensed Patents

“Licensed Patents” are the core of the License Agreement and should be listed in the body of every License Agreement or attached as an appendix. It should be noted that not all Licensed Patents may exist or be approved at the time that the License Agreement is signed. The subject matter of a License Agreement can be a future patent application or a patent application that is still in the early stages of prosecution, so that it still stands for scrutiny in various jurisdictions (according to submission) prior to the award of a patent (if ultimately approved).

It is therefore imperative when defining Licensed Patents to spell out the details of any existing patent application or registered patent, and to clarify that Licensed Patents will include all current and future patents that claim priority therefrom, including corresponding foreign applications.

The definition of Licensed Patents should be crafted to encompass, for example, future patents that cover: (i) existing (and in some cases, future) know-how, even if not included in a Licensed Patent at the time the License Agreement is executed; (ii) future patents that result from the research or that emanate from sponsored research and/or consultancy carried out by the Licensor or the Researcher for the Licensee, so that they are included in the License if not owned by the Licensee by agreement.

For clarity, Licensed Patents sometimes include patent applications that are still pending. Moreover, the definition of Licensed Patents typically also covers the changes and updates that a patent application or a patent may undergo such as: divisionals and continuations, as well as reissues, reexaminations, extensions and restorations. The automatic grant of a License to continuations-in-part and improvements may be subject to deeper scrutiny and discussions between the parties, as the development of the technology could be sponsored by a third party.

Licensed Know-How

The definition of Licensed Know-How is fundamental in achieving a License with a robust scope.

Examples of the form that Licensed Know-How can take are: discoveries and inventions (whether or not patentable) that do not fall within the definition of Licensed Patents, as well as materials, information, data, designs, formulae, ideas, methods, models, assays, research plans, procedures, designs for experiments, and tests and results of experimentation and testing, processes (including manufacturing processes, specifications and techniques), laboratory records, chemical, pharmacological, toxicological, clinical and analytical and quality control data, trial data, case report forms, data analyses, reports or summaries and information contained in submissions to, and information from, ethical committees and regulatory authorities; the common denominator being that this information is not in the public domain or generally known in the industry, at the time of granting the License.

The results of sponsored research and consultation may also be contractually included within the scope of Licensed Know-How.

Parties to License Agreements occasionally neglect to pay sufficient attention to the inclusion of an adequate description of License Know-How which should appear in an appendix to the License Agreement. Ultimately, this can influence the interpretation of the scope of the License and, in certain instances, support an argument on the part of the Licensee, that no royalties are due and payable to the Licensor when the Licensed Patents expire or are found to be invalid.

Moreover, a mechanism and timetable for the actual transfer of the Licensed Know-How from the Licensor to the Licensee should be agreed upon and reflected in the License Agreement. The extent of the support of the relevant Researchers should be clearly defined, if relevant.

Licensed Materials

As mentioned above, Licensed Materials would typically fall within the scope of the definition of Licensed Know-How. The materials in question would need to be proprietary.

The License Grant

The grant provision of the License Agreement determines the extent of the rights in the Licensed Technology which the Licensor grants to the Licensee.
A patent is a negative right, meaning the right to prevent someone else from utilizing the Licensed Technology. Thus, the Licensor allows the Licensee to exploit the Licensed Technology, and the scope of rights would usually include the right to make, use, import, offer to sell and sell Licensed Products, directly and indirectly.
“Directly and Indirectly” means that the Licensee is allowed to carry out these activities through third parties.
A License may be exclusive or non-exclusive.
An exclusive License implies, that the Licensor shall not grant licenses in the Licensed Technology to any third party. If a non-exclusive License is granted, the Licensor may license the Licensed Technology to several parties.
Exclusivity, however, can be subject to various exclusions or caveats.

For example:

- Does exclusivity mean that the Licensor may not exercise such rights itself? Research Institutions, for example, invariably reserve the right to utilize the Licensed Technology for internal research and teaching purposes and for academic collaboration with other Research Institutions;
- Is the License limited to a certain field of use? (more on this below);
- Does the License apply worldwide, or is it limited to a specific "Licensed Territory", which can be a country or geographical area?
- Does exclusivity apply to all of the Licensed Technology? For example, the License Agreement may differentiate between (exclusive) rights to Licensed Patents and rights to Licensed Know-How (that could be non-exclusive).
- Are there legal restrictions that affect exclusivity in certain instances, such as the rights of the Israeli government under the Israeli Patent Law, or a non-exclusive license to the US government required under the Bayh-Dole Act.

The question of exclusivity often depends upon the nature of the IP itself. If the IP consists of a platform technology with diverse applications, the Licensor may strive to license it out to more than one Licensee for different applications, given that a start-up company will usually not have the means to focus on multiple applications which are not in the same field. The Licensee, however, will be interested in the license having the widest possible scope, particularly if the Licensee is an established entity, and will insist on having full control of the development of the technology in all fields.
The same has bearing on questions such as sharing patent costs (more on this below) and litigation against patent infringers. The situation may also create conflicts between Licensees down the road such as one licensee filing a blocking patent which interferes with the exploitation of the license by the other.

FIELD OF USE

Even an exclusive License may be restricted to a specific field of use. For example, a platform technology such as for a pharmaceutical delivery device, may be used in conjunction with multiple drugs. In many cases, the Licensor may be interested in developing the technology for a specific indication itself and/or to license the Licensed Technology out for separate applications or usages to several third parties.
In such cases, the definition of the "field of use" must be carefully drafted. The boundaries of utilization should be clearly marked with a view towards preventing the Licensor from granting conflicting rights to third parties, and the Licensee from breaching the License Agreement by exceeding the scope of permitted use.

Licensed Products

The "Licensed Products" are the result of the commercialization of the Licensed Technology by the Licensee and form the basis of the payment of royalties to the Licensor. A Licensed Product can take the form of tangible products, and/or services.

The definition of the term "Licensed Technology" is of particular significance in the context of a Licensed Product, as a typical definition of the term "Licensed Products" would consist of either or both of the following elements:

A product or component of a product, the making, using, importing, or selling of which, absent the License, infringes the Licensed Patents; or

Which is made with, uses, or incorporates the Licensed Technology.

Licensed Territory

As mentioned in the context of exclusivity, the term "Licensed Territory" is the country or geographic region in which the License may be exercised. While most Licenses confer worldwide rights, some Licenses confine the use of the Licensed Technology by the Licensee to specific places. Moreover, the essence of the rights can also vary, i.e. exclusivity can be granted for part of the world, and non-exclusive rights can be granted for other places.

Sublicensing

A License Agreement may allow sublicensing to third parties simply on the conditions that the sublicensing agreements are made at arm's length (meaning a transaction where both parties are acting independently, without one party being reliant upon the other) and are consistent with the terms of the License Agreement. Other License Agreements impose certain conditions on sublicensing without the prior consent of the Licensor, or simply stipulate that no Sublicense can be granted without the Licensor's consent. The ability to sublicense quickly and efficiently can eventually be crucial to the Licensee as it may become part of an exit scenario.

A "Sublicense" is the grant of a right by a Licensee to a third party, to utilize the Licensed Technology under the License. In effect, the Sublicense "steps into the shoes" of the Licensee for purposes of using the Licensed Technology. A Sublicensee should be differentiated from contractors, who perform services for the Licensee, and from distributors who acquire Licensed Products solely for resale.

Prevalent pre-conditions required by Licensors in relation to Sublicenses can be summarized as follows:

- The sublicensing agreements are made at arm's length and are consistent with the terms of the License Agreement;
- The Sublicense shall be granted for cash consideration (as opposed to payment in kind);
- The Sublicense shall contain provisions necessary to ensure the Licensee's compliance with various provision of the License Agreement (such as warranties, indemnifications, reporting and auditing provisions);
- Generally, the Sublicensee shall not be entitled to grant further Sublicenses to third parties, however, if the Sublicensee is allowed to do so, the extension of rights will stop after one tier;
- The Licensor shall be provided with a copy of all sublicense agreements for review prior to the grant of the Sublicense, and of final versions (full or redacted) following execution.
- A breach of the terms of the License Agreement by the Sublicensee, will be deemed as a breach of the License Agreement by the Licensee.

Moreover, a Sublicense will terminate with the termination of the underlying License Agreement. Thus, in some instances, a Sublicensee will demand to have direct rights from the Licensor through a mechanism known as "step-in rights", in the event of termination of the original License. Some License Agreements already address such eventuality.

The definition of Sublicense has wide sweeping ramifications in the context of the consideration that is due to the Licensor from the exploitation of the Licensed Technology. See the chapters titled "Net Sales" and "Sublicensing Receipts" below.

Royalty Term

The "Royalty Term" is the period during which the Licensee is obligated to pay Royalties to the Licensor on the sale of Licensed Products.

The Royalty Term should be determined in correlation with the nature of the Licensed Technology. A pure patent license will terminate upon the expiration of all "Valid Claims" of the Licensed Patents. The Royalty Term under a license for a combination of patents and know-how will usually terminate upon the latter of (i) the expiration of all "Valid Claims" of the Licensed Patents; and (ii) a certain number of years following the first commercial sale of the Licensed Product.

"Valid Claims" is a term used to describe a situation whereby a claim of a patent application included within the Licensed Patents is pending or such claim has been allowed and has not expired or been held invalid.

It should be noted that the Royalty Term is often determined on a country-by-country and Licensed Product-by-Licensed Product basis so that the obligation to pay royalties may end in relation to one Licensed Product in a certain country but continue in relation to other Licensed Products or the same Licensed Product when sold elsewhere.

While the expiration of all Valid Claims does not necessarily trigger the end of the Royalty Term, some License Agreements provide for a reduction of the royalty rate in countries where there are no Valid Claims.

Diligence

Given that the Licensor is interested in commercializing Licensed Technology and that the consideration payable to a Licensor under a License Agreement is often linked to the successful development and commercialization of a Licensed Product, a Licensee must demonstrate that it is using commercially reasonable efforts to complete development and to market, distribute and sell Licensed Products, either directly or through its Affiliates and Sublicensees.

These diligence provisions that bind Licensees under a License Agreement are referred to as "anti-shelving provisions". Anti-shelving provisions may include general "best commercial efforts" clauses or specific milestones that the Licensee must meet to preserve its rights.

An exclusive license will most likely include an obligation by the Licensee to carry out an agreed development program and to achieve certain milestones within a prescribed time frame. These obligations can apply to one or more Licensed Products.

If the License Agreement contains contingent payments in consideration for the license, it will usually require the Licensee to submit progress reports so that the Licensor can assess the Licensee's diligence.

Failure to expend commercially reasonable efforts and/or to achieve agreed milestones may entitle the Licensor to terminate the License. As achieving certain milestones may be out of the Licensee's control (such as by reason of technical or regulatory issues), a License Agreement may include certain cure periods during which a Licensee will be afforded the opportunity to remedy the situation.

Reporting

Further to the point raised above, Licensing Agreements may require the Licensee to periodically provide the following reports:

- Progress reports regarding the development and commercialization of Licensed Products and projections;
- Reports on meeting various milestones;
- Reports on Net Sales and Sublicensing receipts;
- Report of receipt of regulatory approvals;
- Report of first commercial sale per country.

Failure to submit such reports will typically constitute a breach of the License Agreement.

Representations and Warranties; Indemnities

Representation and warranties are declarations provided by each party to an agreement to the other party to the agreement. Should any of these declarations prove to be inaccurate, the breaching party will be liable to indemnify the other party for its losses.

Consequently, Licensors in general and Research Institutions in particular, are very careful not to provide extensive representations and warranties in relation to the Licensed Technology. In the case of Research Institutions, such representations and warranties are usually limited to ownership and control of Licensed Technology, and to a declaration that the Licensor is not aware of any demand or claim regarding the Licensed Technology infringing third party rights. In most cases, at the time a License Agreement is signed, there can be no certainty that the License Technology will result in a viable Licensed Product, or that the Licensed Technology is not infringing intellectual property rights anywhere in the world. Moreover, the Licensor should disclose any third-party rights or funding that applies to the Licensed Technology and which may affect the scope of the License.

On the other hand, a Licensor will usually insist on being fully protected against damages that may arise from the use of the Licensed Technology by the Licensee, its Affiliates and Sublicensees. The only exception to this, if at all, will be the gross negligence or willful misconduct of the Licensor or its employees.

Patents

Patent Prosecution and Protection

The involvement of an exclusive Licensee in prosecution of the Licensed Patents varies per License Agreement. In some instances, the Licensor remains in control of the process and undertakes to confer with and to provide a right of review to the Licensee. In other cases, the opposite is the case.

As mentioned above, the Licensee will often assume all patent expenses. Both parties have an interest in the patent being awarded in as many jurisdictions as possible, but this is an expensive exercise. The Licensor will therefore often demand that the patent be prosecuted and maintained, at least in certain major jurisdictions.

Abandonment of Licensed Patents on the part of the Licensee may lead to the loss of the License in the jurisdictions where the Licensed Patents are abandoned. Abandonment of patents in the major jurisdictions identified by the Licensor as mentioned above, may result in the loss of the License as a whole.

In the case of a non-exclusive License, the Licensor may retain control of patent prosecution.

Infringement of Third-Party Proprietary Rights

The Licensor will strive to protect itself through the License Agreement, so as not to have any liability if the Licensee is infringing third party intellectual property rights while exploiting the License and is sued by a third party.

The License Agreement will, however, commonly contain detailed provisions in relation to alleged third party infringements of the Licensed Technology. The License Agreement will detail which party can pursue the alleged infringer, notice and information requirements, the scope of authority of the party who pursues the alleged infringer in an attempt to reach a settlement, the assumption of costs, and how any award in favor of the suing party against the infringer will be divided between the parties. For example, this division may be identical to the percentage used in relation to Sublicensing Receipts, after the suing party recovers its costs.

Terms

The effective term of a License Agreement is identical to the Royalty Term. If the Royalty Term is applied on a country-by-country and Licensed Product-by Licensed Product basis, a License Agreement may remain in force and effect over an extensive period.

Termination/Expiration of a License Agreement

A License Agreement may terminate or expire for various reasons:

- Termination for convenience – the Licensee wishes to terminate the License for no reason or any reason, such as a lack of interest or no commercial viability;
- Termination for breach – either party may seek to terminate the License Agreement for a material breach i.e., a breach that is not remedied following prior notice, within the agreed cure period or according to the law;
- Termination for bankruptcy;
- Termination by Licensor upon challenge of the validity of the Licensed Patents;
- Lapsed – the License Agreement will automatically expire in accordance with its terms, usually when all of the Royalty Terms under the License Agreement have elapsed;
- Failure by Licensee to meet certain prior conditions – such as failure to raise capital;
- Failure on the part of the Licensee to achieve milestones.

While most of these scenarios are normally covered in the License Agreement, the inclusion of a termination for convenience clause, which is beneficial to the Licensee, is subject to negotiations between the Parties.

The cure period afforded to the Licensee to correct failures such as non-compliance with milestones, if any, depends on the provisions of the License Agreement.

Effect of Termination/Expiration

The effect of termination or expiration of a License Agreement is dependent upon the circumstances under which the License was terminated.

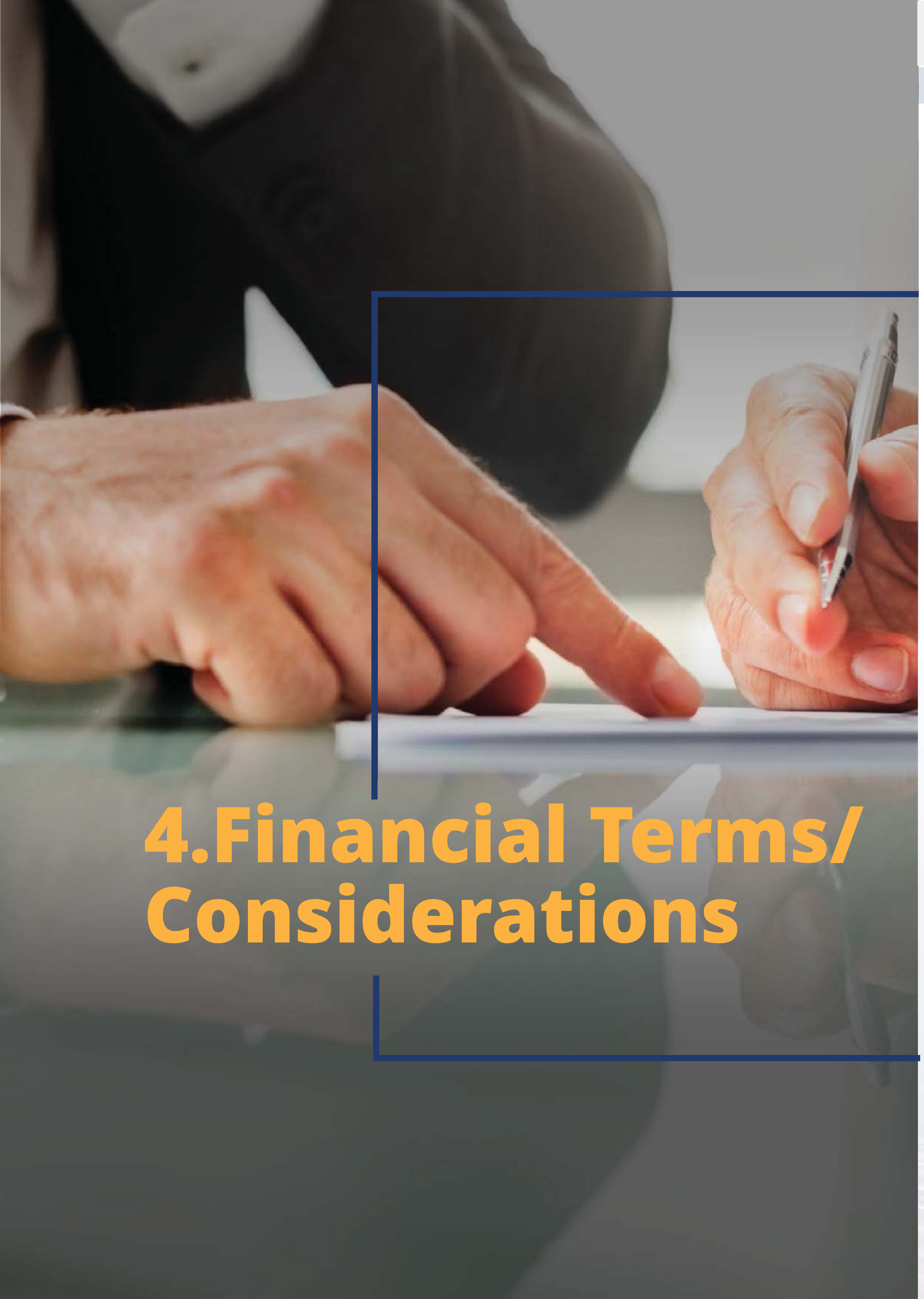
In principle, the Licensee shall not be entitled to make any further use of the Licensed Technology or engage further in the development, manufacture, marketing, distribution, or sale of Licensed Products. The Licensor may also have the right to demand that the Licensee transfer regulatory approvals and know-how relating to the Licensed Products developed by the Licensee, its Affiliates and Sublicensees, to the Licensor on terms and conditions to be agreed upon.

A Sublicensee may have step-in rights, as mentioned above.

Other provisions

The following is a list of additional provisions that may be included in License Agreements:

- Accounting/ audits
- Confidentiality
- Publications
- Assignment
- Applicable law
- Arbitration
- Marking of Licensed Products
- Notices
- Severability
- Entire Agreement
- Electronic signatures



4.Financial Terms/ Considerations

Financial Terms/ Consideration

Evaluating technology, particularly in its early stages, is not an exact science. In some cases, the Licensee is willing to take a higher risk and to pay a higher immediate upfront payment and milestone payments and, consequently, pay lower royalties in the future.

Some Licenses only require a one-time lump sum or annual payment. It should be noted, however, that the components of the consideration payable for a License will vary according to the subject matter. For example, the financial terms prevalent in the pharmaceutical field are different than those that are usually found in the medical device or digital health sectors.

These may include any or all of the following (not an exclusive list):

- Upfront Payment
- Annual licensing fees
- Payments on Sublicense receipts
- Milestone Payments
- Running royalties
- Reimbursement of prior patent expenses (see chapter on patent expenses)
- Exit Fees
- Equity

Upfront Payment

A demand by a Licensor for an upfront payment from a Licensee is more common when (i) the Licensed Technology is in an advanced stage of development, when the risk of developing the Licensed Technology into a Licensed Product assumed by the Licensee, is lower; and (ii) when the Licensee is an established company.

Some Research Institutions, however, demand an upfront payment to reflect the resources that have already been devoted to developing the technology and/or as an administrative fee to cover the time and expense devoted by the Research Institution to entering into the License Agreement. It should be noted that, in most cases, technologies emanating from Research Institutions are very early-stage, high-risk, and require significant investments in order to reach the market.

Upfront payments are usually non-refundable and not creditable against future royalties.

Annual Licensing Fee

A License Agreement will often contain the requirement that the Licensee pay an annual license fee to retain the License. This serves as an "anti-shelving" mechanism, i.e. to ensure the Licensee's diligence in continuing to develop the Licensed Technology and to bring Licensed Products to the market.

License fees become payable on an annual basis, commencing a specified period following the effective date of the License Agreement. Moreover, in most cases, the License Agreement allows a set-off of these fees against certain royalty payments. They can either be creditable against all cumulative royalty income or, more commonly, creditable only against royalties that are collected during the year in respect of which the annual license fee was made.

Milestone Payments

Milestone Payments reflect the increased value of the Licensed Technology. The milestones that trigger payments can either be development milestones or commercial milestones. The following are examples of development and commercial milestones, the achievement of which may trigger Milestone Payments:

- In the case of pharma and medical devices: various pre-clinical and clinical phases of development.
- Annual or cumulative revenues derived from the sale of Licensed Products that become blockbusters.

A License Agreement may stipulate that the achievement of the milestone that triggers a Milestone Payment can be attained by the Company, its "Affiliate" (meaning a related entity) or a Sublicensee. In such event, it is important to ascertain that there is no "double dipping" due to the Licensor based on a Milestone Payment and Sublicensing Receipts (see below).

Running Royalties

Running royalties are payments that are derived from the sale of Licensed Products, throughout a defined period of time (more on this below).

The calculation of royalties can be based on a fixed price per unit varying by sales volumes but is more commonly made as a percentage of an agreed royalty base, which is usually defined as "Net Sales".

Careful attention should be given to the various elements that make up the definition of Net Sales:

- Is the calculation made on the basis of the sum actually collected or invoiced? In the latter case, there should be a provision allowing for the deduction of bad debts;
- Is the calculation based on the sales of the Licensee and its Affiliates or does it also include the sales of Sublicensees? (more on this below);
- Does the definition apply to all sales (including to distributors) or is the calculation based on sales to end-users?
- Does the definition include typical exclusions (if included within the amount charged but separately billed), such as (i) import, export, sales tax (VAT) and custom duties: (ii) costs of insurance, packing and transportation; (iii) credit for returns, allowances or trades?

The definition of Net Sales may also contain a mechanism for determining the fair market value of Licensed Products, which are transferred to third parties, free of charge.

While all the factors comprising the definition of Net Sales are material, it is particularly essential to understand the addition of sales by a Sublicensee (known as a "pass-through) in this equation. This means that the Licensor will still receive what they would have received had the direct Licensee sold the Licensed Product. The result may prove financially unplausible for a Licensee who does not attain a high enough royalty rate from its Sublicensee. There may also be discrepancies in the way Net Sales are accounted for under each agreement. On the other hand, the Licensor may have a legitimate interest in ensuring that a sublicensee is committed to pay sufficient royalties on the sales of Licensed Products. Due to these concerns, the parties sometimes adopt special formulas such as determining a minimum and maximum sum that will be due to the Licensor on Net Sales of the Sublicensee, or the Licensor being entitled to a certain percentage of all sublicensing income received by the Licensee from the Sublicensee, including in respect of sales of a Licensed Product.

It should also be noted that the ultimate royalty percentage may vary depending upon the following factors:

- The type of Licensed Product (for example, therapeutic, diagnostic or a medical device)
- The total of Net Sales
- Deduction of royalties paid to third parties (known as "anti-stacking") (see below)
- If the Licensed Product is combined with or bundled together and sold in combination with other products that are not Licensed Products (see below)
- Whether or not the Licensed Product is protected by a Valid Claim (see definition below). If not, the royalty rate may be reduced so as to reflect only the value of the Licensed Know-How.

Anti-stacking

Many technologies are licensed-out at a very early stage of development, when it is not yet economically feasible or even possible to conduct worldwide patent searches to ensure that the Licensed Technology will be non-infringing. Moreover, at an early stage of product development, it is impossible to know whether any third-party technologies will be necessary or useful in bringing a Licensed Product to market. Thus, some License Agreements allow the Licensee to deduct third party royalties, or at least a certain portion thereof, from payments that become due to the Licensor. Otherwise, the royalty burden of multiple licenses may become too heavy for a Licensed Product to be financially viable.

Combination Products

A Licensed Product may be sold as a stand-alone product, or incorporated into, combined or bundled with other stand-alone products. License Agreements often address this issue by defining a “Combination Product” and setting out a formula for allocating value to each stand-alone component. This allows the parties to attribute to the Licensed Product the appropriate sums of revenue generated by the sale of the Combination Product, for purposes of calculating the consideration due to the Licensor.

Generic Competition

Certain License Agreements allow for a reduction in royalty rates if there is generic competition to the Licensed Products in major markets

Payments on Sublicensing Receipts

Sublicensing Receipts are payments that are paid to the Licensor by the Licensee on the basis of payments received by the Licensee and its Affiliates for the grant of Sublicenses.
Sublicensing Receipts will typically be listed, as illustration of the various payments that can be considered as such. These include upfront payments, annual license fees, license option fees, milestone payments, license maintenance fees and equity.
It is common to exclude the following from the scope of Sublicense Receipts, with certain provisos:

- Net Sales of the Sublicensee (if they are included in the general definition of Net Sales that triggers royalties);
- Equity investments in the Licensee and its Affiliates which reflect market conditions;
- Payments made to the Licensee for contract R&D to develop the Licensed Technology;
- Reimbursement of patent expenses.

Exit Fee

Should the Licensed Technology be licensed to a startup company, the Licensor may demand an Exit Fee. The Exit Fee will be payable only upon an “Exit Event”, typically defined as an IPO, M&A, or liquidation. The Exit Fee will be calculated as a percentage of the consideration received by the Licensee, its Affiliate or shareholders (depending upon the nature of the event).

Equity

Should the Licensed Technology be licensed to a startup company, the Licensor may expect to receive equity in the Licensee as full or partial consideration.

Often there are various undertakings that are assumed by the Licensee in relation to such equity, such as anti-dilution protection over a certain period of time, or until a certain amount is invested in the Licensee.

It should be noted that License Agreements rarely provide for consideration both in the form of Equity and Exit Fees.

Some Licensors do not wish to assume the position of a shareholder. Others may have the means (either directly or through affiliates) to invest in the Licensee to avoid massive long-term dilution of their holdings in the Licensee. Such Licensees may demand certain rights to be conferred by their shareholdings in the Licensee, such as preemptive rights or the right to appoint a member of the Licensee's board of directors, or an observer.

Patent Expenses

Differentiation should be made between patent expenses incurred by the Licensor prior to the effective date of the License Agreement, and those incurred thereafter.

Many License Agreements, particularly when the Licensor is a Research Institution, stipulate that the Licensee must reimburse the Licensor for patent expenses incurred prior to the effective date of the License Agreement. These expenses may be quite substantial, depending upon how long ago the Licensed Patent was filed. In the event of start-ups, a payment schedule can be negotiated.

A Licensee may be bound to assume the ongoing payment of patent expenses once the License goes into force and effect.

If the License is non-exclusive, the Licensee should strive for the expenses being allocated between all Licensees.

5.Conclusion

Conclusion

A License Agreement, especially in the pharma sector, is designed to secure the long-term rights and obligations of the parties. Consequently, a License Agreement is a complex document, the negotiation and drafting of which can be a long and complicated process. This is, among others, due to the various ways a technology can be developed, the forms and applications that products can take, the various business models companies can implement and change, and the protracted timeframe over which a Licensed Product is developed, marketed and sold.

It is therefore important that you familiarize yourself with the basic concepts detailed in this playbook, as a precise and detailed understanding of the various issues in the License Agreement can have far-reaching commercial ramifications.

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