



Licensing: Dissecting a Standard Agreement

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Training School

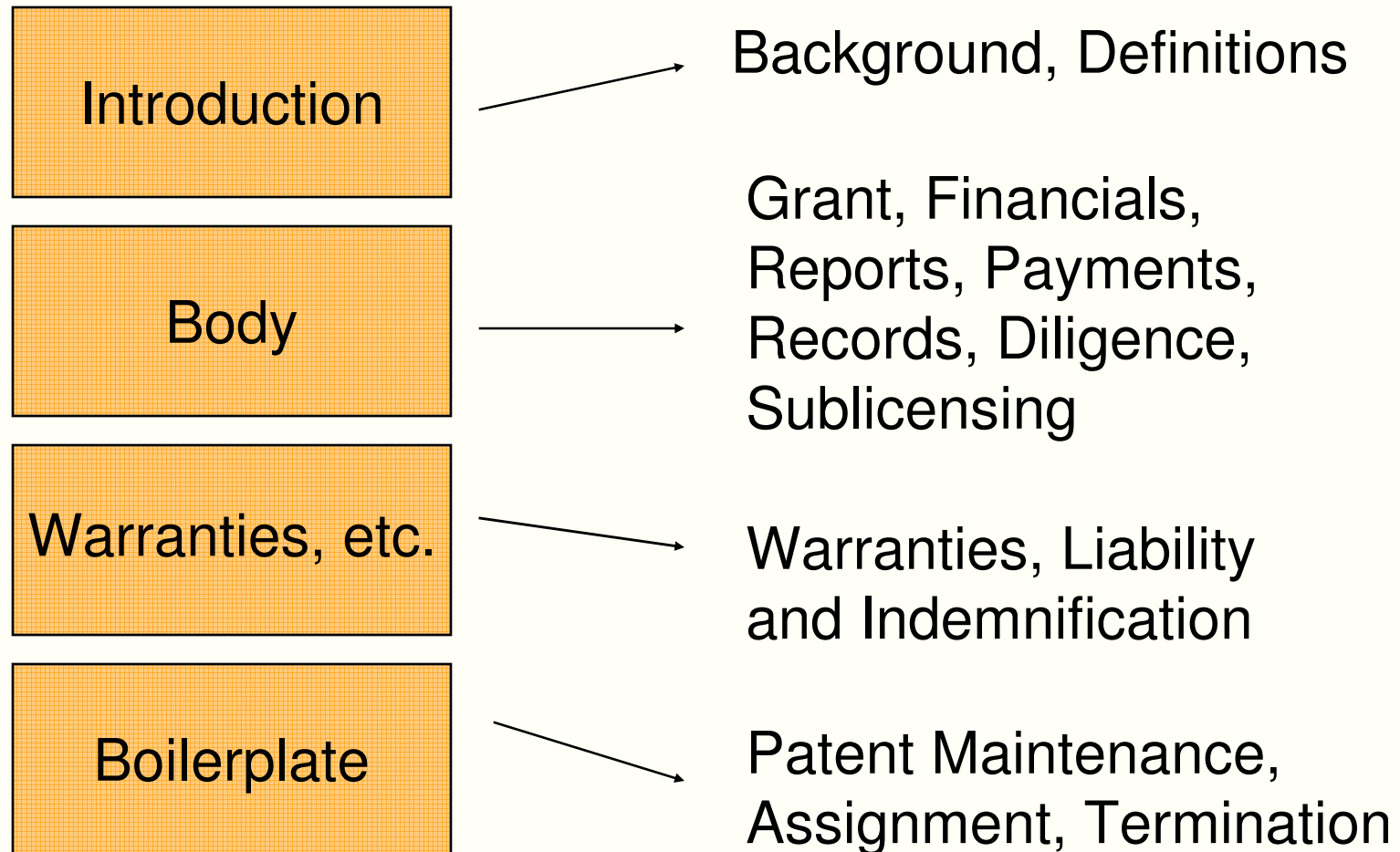
Making Transfer Offices a Success

Ferrara, November 21,

What is a license?

- Legal instrument to maximize utility of intangible asset (where licensee is better positioned than licensor to exploit)
- Balance between utility for the licensor and utility for the licensee, such that both benefit.
- Maximum utility means:
 - Limited opportunity loss, exclusive versus non exclusive, retained rights
 - Risk – reward – other forms of compensation – access to improvements, etc.

Map of a License Agreement



Recitals

- Introduces the parties
- Introduces the technology
- Explains the reason for doing the license
- Important: may note previous arrangements between the parties
- Often uses 'Whereas' clauses
- Only used to interpret the other clauses

Recitals: *examples*

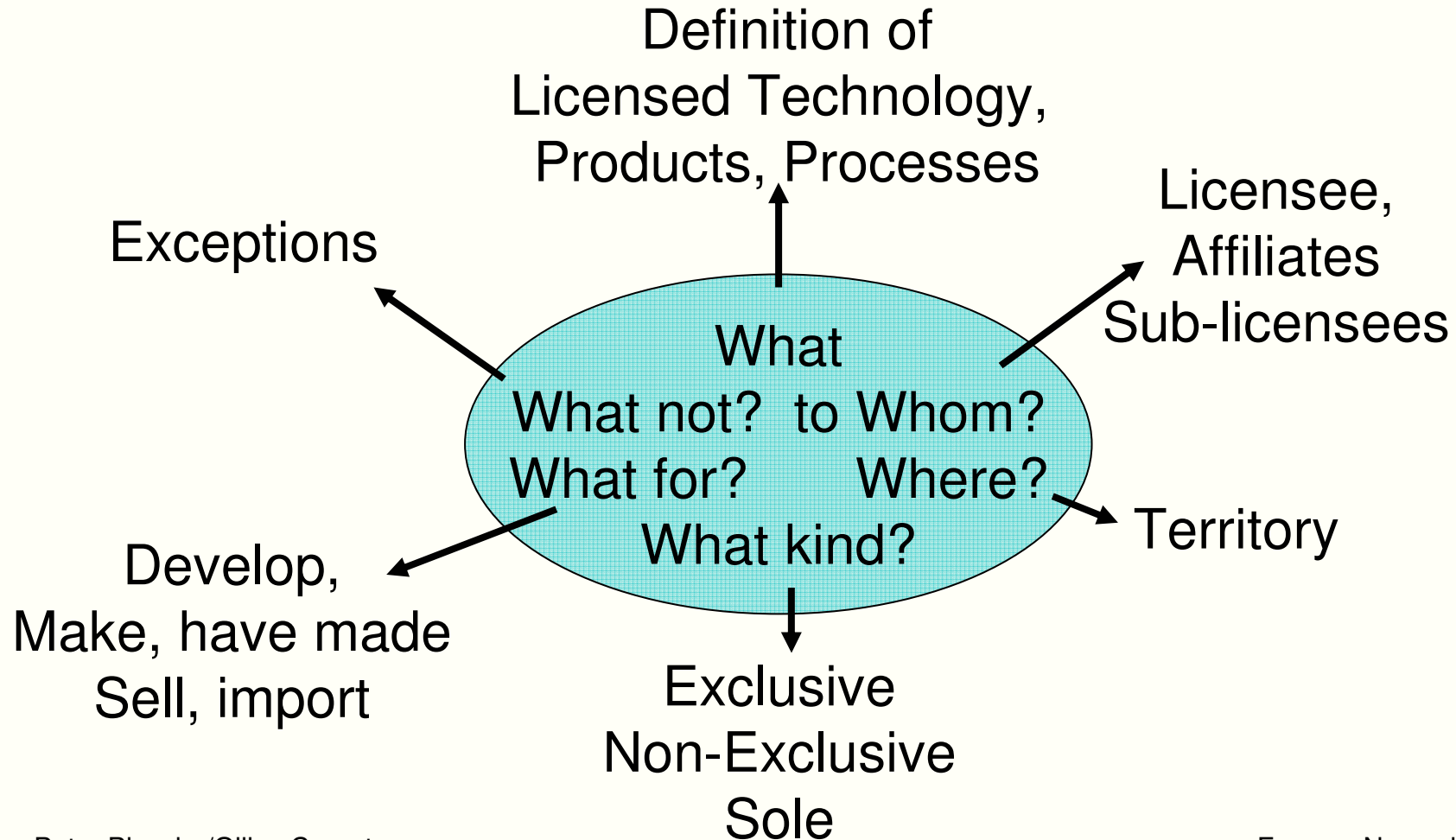
- University desires to have Invention perfected and marketed at the earliest possible time in order that products resulting therefrom may be available for public use and benefit.
- Licensee desires a license under said Invention to develop, manufacture, use and sell Licensed Products.
- Licensee previously entered into an option agreement with University and now wishes to exercise its option.

Value chain analysis

It is critical to analyse in details how the licensee intends to use the licensed technology in the value chain. This will determine:

- What needs to be licensed
- On what basis the consideration should be calculated
- Other potential benefits for the licensor

Grant : the place to start



Grant

- What the licensor (Institute) is giving to the licensee (Company)
 - What kind of license it is (exclusive, non-exclusive)
 - What it is for (patent rights, materials)
 - In what areas they can practice the technology (field of use, territory)
- What the Institute is not giving to the Company
 - Retain the right to use your technology!

Grant : *example*

- INSTITUTE herewith grants to COMPANY an exclusive license, (with right to sub-license), for the manufacture, the use and the sale of **Licensed items** under **Licensed Technology** in the **Field** in the **Territory**.
- INSTITUTE, however, maintains the right to use the **Licensed Technology** for its own educational, clinical and scientific purposes including cooperation with third parties.

Licensed Technology (definitions)

- Detailed list of exactly what is being licensed:
 - Patents? (list in appendix)
 - Know how? (confidentiality provisions)
 - Copyrights? (software, data bases, results, studies, ..)
 - Trademarks
 - Materials, etc..
- Embodied in Products?, Processes?
- As existing on Effective Date or with access to improvements?

Other key definitions

- **Field:** what applications are licensed?
- **Territory:** in which countries?

The grant should only cover what the Licensee commits to exploit and is well positioned to do so

Financials/Royalties

Main considerations in choosing the forms of payment:

- Risk sharing
- Timing of revenues
- Practicability of calculations

Many types of payments to chose from:

- Upfront Payment
- Annual Minimums
- Running/Earned Royalties
- Patent Expenses - past and/or future
- Milestone Payments/Lump Sum (creditable or not)
- Fully Paid (Single Payment)

Royalties continued

- Types of milestone payments:
 - Therapeutics: Upon IND filing, initiation of Phase I, II, III Clinical Trials, NDA filing, FDA approval
 - Prototype
 - First commercial sale
 - Strategic Partner signed
 - Funding (e.g. €1,000,000)
 - Patent Grant
 - Proof of Concept
 - Number of years of survival of agreement

More on Royalties

- Earned Royalties
 - Can be:
 - a percentage
 - a set amount per item
 - scaled gross amount per sales
 - Definition of Net Sales (or whatever you are deriving your earned royalties from
 - Gross sales minus any deductible expenses both parties agreement on (e.g. returns, certain taxes)

Reductions

- Combination products (allocation of revenues to the components)
- Anti-stacking clauses (when licensee is obligated to pay royalties to other parties in order to exploit the technology)
 - Example: credit of 50% of royalties due to other licensors up to maximum 50% of royalties due to licensor.(50/50 clause)

Financials: *example*

- Upon signing this Agreement, Licensee shall pay to Licensor a noncreditable, nonrefundable up-front fee of ...("Up-front Fee").
- Licensee shall pay Licensor ...annually from the Effective Date for use or sale of the Products ("Annual Minimum"). Annual Minimum(s) are payable and deductible against accrued Royalties. Licensor shall invoice the Licensee for the minimum royalty payment at the beginning of each calendar year and Licensee shall make the payment within 30 days after receiving the invoice.

Reports, Payments, Records

- Will you receive updates on the company's development progress? How often?
- How often will you receive earned royalty reports and payments?
- What sort of records should the company keep? What are your auditing rights?

Royalty reports & payments: *example*

COMPANY shall deliver to ITALIAN INSTITUTE, within ninety (90) days after the end of each calendar quarter, if relevant, reasonably detailed written accountings of Net Sales of Licensed Products that are subject to royalty payments due to ITALIAN INSTITUTE for such calendar quarter.

Royalty reports & payments: *example*

Such quarterly reports shall indicate gross sales on a country-by-country and product-by-product basis, the deductions from gross sales used in calculating Net Sales and the resulting calculation of royalties.

When COMPANY delivers such accountings to ITALIAN INSTITUTE, COMPANY shall also deliver all royalty payments due under Section 3.4 to ITALIAN INSTITUTE for the calendar quarter.

Records and auditing: *example*

- Licensee shall keep and maintain reasonably adequate books of account relating to the manufacture, use, distribution, sales and other disposition of the Products.
- With thirty (30) days written notice to Licensee, Licensor may at its own expense audit the applicable records in order to verify the amounts of the Products and Royalties hereunder.

Records and auditing : *example*

- Any possible audit shall be conducted during business hours and in such manner as not to interfere with Licensee's normal business activities.
- If the audit materially differs with statements provided by Licensee, Licensee shall be responsible for all incurring costs of such audit.

Sublicensing

- Exclusive vs. Non-exclusive
- Allow sublicensees to further sublicense?
- What should the sublicense agreement include (provisions from this Agreement)?
- What is the Institute getting from the sublicense?
 - Earned royalties
 - Share of payments other than royalties
 - R&D payments/expenditures

Sublicensing : *example*

- Sublicenses for the Agreement Patent Rights can only be granted by COMPANY after prior written consent of DKFZ. COMPANY will send a copy of any sublicense contract to DKFZ.
- Any sublicense will specifically include the provisions of §8, §9, §10 and §12 Section 2 and will specifically state that sublicensee does not have the right to further sublicense the Agreement Patent Rights.

Sublicensing : *example*

- If COMPANY is unable or unwilling to develop a certain field of the Agreement Patent Rights for which there is a willing sublicensee, COMPANY agrees to negotiate with this third party for a sublicense to the Agreement Patent Rights.
- If this Agreement terminates for any reason, any sublicensee will become the direct licensee of DKFZ.

Diligence

- Basic – that Company undertakes to diligently develop the technology into a product (minimum standards of the profession, same diligence as own products with similar potential)
- But include more – specific milestones
- Termination if Company cannot fulfill its obligations

Diligence: *example*

- COMPANY is obligated to exploit the licensed rights with diligence (test to be specified).
- Failure to exploit the Agreement Patent Rights is just cause for DKFZ to terminate this Agreement with thirty (30) days written notice to COMPANY.
- COMPANY agrees to meet the development and product milestones for the Agreement Patent Rights set forth in **Exhibit B**.

Diligence: *example*

- If COMPANY fails to meet any of these milestones, DKFZ may terminate this Agreement with thirty (30) days written notice to COMPANY. In each case, if COMPANY (1) rectifies the failure and provides DKFZ with ample proof of this rectification before the thirty (30) days is over or (2) comes to a new agreement with DKFZ regarding the milestones, then the termination will not go into effect.

Representations, Warranties, Liabilities & Indemnification

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- **What is a representation?**
 - a statement on which the other party has relied to enter the agreement
- **What is a Warranty?**
 - “a written guarantee of the integrity of a product...”
- **What is Indemnification?**
 - security against hurt, loss, damage or liability for licensed technology
- **What is Liability?**
 - responsibility

R, W, L and I cont.

- **Things to warrant**
 - That you own the technology
 - That you have the right to enter the agreement
- **Things to represent**
 - As little as possible
 - Only in good faith, to the best of knowledge
- **Things to consider:**
 - What risks is your institution willing to take?
 - What kind of insurance do you have?
 - Do you want the company to insure you?

Liability: *example*

- Neither Party shall be liable to the other Party for any incidental, consequential, special, or punitive damages of any kind or nature, including, without limitation, the breach of this Agreement or any termination of this Agreement, whether such liability is asserted on the basis of contract, tort (including negligence or strict liability), or otherwise, even if either Party has warned or been warned of the possibility of any such loss or damage.

Liability: *example*

- In any case the total liability shall not exceed the total value of the paid Royalties and other compensation. The aforementioned limitation of liability shall not be applied to cases of gross negligence, willful misconduct or breach of clause 7 (Proprietary Rights & Infringement) or 9 (Confidentiality).

Warranties (or the lack thereof): *example*

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- COMPANY understands and acknowledges that DKFZ, by this Agreement, makes no representation as to the operability or fitness for any use, safety, efficacy, approvability by regulatory authorities, time and cost of development, patentability, and/or breadth of the Agreement Patent Rights.

Warranties (or the lack thereof): *example*

- DKFZ, by this Agreement, also makes no representation as to whether there are any patents now held, or which will be held, by others or by DKFZ which may be dominant or subordinate to Agreement Patent Rights, nor does DKFZ make any representation that the inventions contained in Agreement Patent Rights do not infringe any other patents now held or that will be held by others or by DKFZ.

Indemnification: *example*

- COMPANY agrees to hold harmless, indemnify and defend DKFZ, its officers, employees and agents from and against any claims, demands, or causes of action whatsoever, including without limitation those arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the license granted hereunder by COMPANY, its sublicensees, or their officers, employees, agents or representatives.

Patent Maintenance and Infringement Procedures

- **Non-exclusive vs. Exclusive**
 - Non-excl: simple, Institute is decision-maker
 - Excl: Who is responsible for maintaining and prosecuting? Who proceeds with infringers? Who receives what on outcome?
- **Non-exclusive without materials**
 - Is Institute required to maintain the patents?

Patent Maintenance: *example*

- Simple: DKFZ will maintain the Agreement Patent Rights for the duration of this Agreement.
- More complicated: ITALIAN INSTITUTE shall consult reasonably in advance with COMPANY on each step of the filing, prosecution, maintenance and extension and on all other related proceedings (i.e., interferences) and shall promptly furnish to COMPANY copies of all documents relevant to any such actions and shall consider and incorporate

Patent Maintenance : *example*

- COMPANY's suggestions with respect to the foregoing whenever reasonable; provided, however, that final decision making authority shall vest in ITALIAN INSTITUTE in all areas, applications and clinical indications of the Patent Rights, except in the Field. Exclusively limited to this Field, COMPANY shall have the authority to make final decisions on the Prosecution.

Patent Infringement (excl. only)

- Each Party agrees to notify the other Party promptly of each suspected or confirmed infringement of the Patent Rights such patents of which that Party is or becomes aware.
- COMPANY shall have the right to prosecute in its own name and at its own expenses any infringement of the Patent Rights in the Field.

Patent Infringement cont.

- If COMPANY is involved in any litigation regarding the assertion or enforcement of its interest in the Patent Rights in the Field and/or infringement of the Patent Rights in the Field, ITALIAN INSTITUTE upon request of COMPANY shall cooperate fully with COMPANY, and COMPANY shall reimburse ITALIAN **INSTITUTE** for all reasonable out-of-pocket expenses in connection with any such assistance.

Patent Infringement cont.

- Recoveries or reimbursements from actions commenced pursuant to this Section 4.4 shall first be applied to reimburse COMPANY for all litigation costs. Any remaining recoveries or reimbursements shall be treated as Net Sales hereunder.

Patent Infringement cont.

- If COMPANY does not institute an action within 30 days after receiving notice from ITALIAN INSTITUTE or otherwise being informed of an infringement of the Patent Rights in the Field, then ITALIAN INSTITUTE may, at its sole discretion and expense, institute an action with respect thereto, and any recovery obtained shall belong to ITALIAN INSTITUTE .

Assignment

- Assignment – allowing the licensee to transfer the rights to another party
- Why should you allow a company to assign?
 - Companies are ever-changing (mergers, acquisitions, sell-offs)
 - Shows flexibility, willingness to do the deal
- Why should you not allow a company to assign?
 - Not the company and people you chose to do the deal with!
- Assignment fee idea

Assignment : *examples*

- Licensee does not have the right to assign this Agreement.
- Neither Party may sell, transfer or assign its rights (including the license granted herein) and duties under this Agreement without the written consent of the other Party, which consent shall not unreasonably be withheld.

Assignment : *example cont.*

- COMPANY may assign this Agreement as part of:
 - a sale of other transfer of COMPANY's entire business; or
 - a sale or other transfer of that part of COMPANY's business to which the license granted hereby relates,upon payment by COMPANY to DKFZ of an assignment fee of Fifty Thousand Euros (50,000 EUR).

Term and Termination

- Important points (based on risk analysis):
 - How long will the license last? (e.g. 10 years from Effective Date, from sale of first products, life of licensed patent) (antitrust limits)
 - What happens beyond the term (fully paid-up license if not in default)
 - Extension of term (on improvements)
 - When can each party terminate?
 - How do the notices for termination work?
 - Can either party try to remedy any defect?

Term and Termination

- What does termination mean?
 - Can the Company still sell products in inventory?
 - Does the Company need to return material?
- What survives termination?
- Governing law regarding notices

Term and Termination : *example*

- Term: The Agreement shall remain in full force and effect for five (5) years, and whereafter it will be automatically renewed for twelve (12) months at a time, unless terminated by either Party by written notice at least four (4) months prior to the end of such period of twelve (12) months.

Term and Termination: *example*

- Company's right to terminate: COMPANY shall have the right to terminate this Agreement at any time upon thirty (30) days prior written notice to ITALIAN INSTITUTE.

Termination cont.

- ITALIAN INSTITUTE shall have the right to terminate this Agreement in the event of default or failure by COMPANY to perform any of the terms, covenants or provisions of this Agreement, and COMPANY shall have sixty (60) days after the giving of written notice of such default by ITALIAN INSTITUTE to correct such default unless a shorter time period is specified below. If such default is not corrected within time period for cure, ITALIAN INSTITUTE shall have the right, at its option, to terminate this Agreement. In particular ITALIAN INSTITUTE may provide notice of termination in accordance with this Section should one or more of the following occur:

Termination cont.

- If COMPANY does not make a payment due hereunder and in such an event fails to cure such non-payment (including the payment of patent costs and the payment of interest in accordance with Section 3.4(h) within forty-five (45) days after the date of notice in writing of such non-payment by ITALIAN INSTITUTE ;
- If COMPANY defaults in its obligations under Sections 8.2 to procure and maintain insurance;

Termination cont.

- If COMPANY shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it. In such an event, the termination shall be effective immediately upon **ITALIAN INSTITUTE** giving written notice to COMPANY;

Further Areas of Discussion

- Confidentiality
- Names/Marks
- Governing Law
- Notices
- Import/Export Laws
- Severability

License administration

- Monitoring system in place
- Many licensees forget to pay
- Auditing rights are very useful, consider using professionals
- Report to stakeholders

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