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Guidelines for Preparing a Technology Transfer Agreement

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Outline

- **Why TT agreements are important?**
- **Patents at the core of business**
- **Main types of TT agreements and key provisions**
- **General and commercial / Financial considerations**
- **Model TT agreements!!!**
- **IP due diligence in preparation of TT agreements**
- **IP investigation / assessment**
- **TT agreement checklists**
- **Final considerations and policy implications**

Technology Transfer – A Complex Process

- **Complex and long drawn-out process**
- It deals not only with technology as the subject of transfer, but also **addresses issues related to administration, planning, management, marketing and implementation.**
- The complexity of the process often leads to **difficulties and sometimes even failures**
- The problems are generally attributed to the **lack of systematic guidance in planning, control, monitoring and decision-making.**

Technology Transfer, if carefully planned and implemented, brings significant benefits in terms of both time and cost savings.

Stages of Technology Transfer

An Investor's perspective

- Technology needs assessment
- Identifying sources of technology
- Specifying the technology / supplier
- Tech transfer negotiation
- **Technology Transfer agreement**
- Technology transfer implementation

Why TT Agreements are Important?

- **Promoting business relationship**
- **Establishing contractual agreement** that is binding on both parties and enforceable under legal provisions.
- **Dealing with intellectual property (e.g. patents, copyrights, trademarks, industrial designs) – ownership, licensing, royalty**
- **Accessing technologies**
- **Providing flexibility of coverage** over one or more types of intellectual property rights

Why TT Agreements are Important?

(Cont'd)

- **Addressing contractual problems** between parties by referring to the respective clauses written in the TT agreement.
- **Addressing trans-national issues**
- **Facilitating non-licensing technology transfer** relating to processes, know-how and trade secrets
- **Delineating the object of technology transfer** - manufacturing of new products, penetrating new markets, litigation rights, taxation, legal and accounting

Commercialization of Patents in the Shoes of Investors

- Commercial ventures based on new patents could be **capital-intensive** and investments have **long payback period**.
- Investors look for **clear ownership of Intellectual Property (IP)**
- Investors are well aware of the **centrality of patents** in the industry and will conduct a thorough **due diligence** prior to taking a decision to invest.
- Investors will seek to determine whether the company will have **freedom to operate**, i.e. whether it will be able to commercialize the product **without any IP infringement**.

Source: http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html

Tracking Market Trends

Certain trends in ‘**medical biotech sector**’ an investor/company tracks:

- Aging population and their healthcare needs
- Global reach of certain diseases
- Global trends in vaccination coverage
- Obesity and diabetes trends
- Technological advances

Patents at the Core of Business

Inventions need to fulfill **three basic requirements of patentability**:

- Novelty
- Inventive step or non-obviousness
- **Industrial application or utility**

These should be borne in mind while:

(a) Drafting patent applications

(b) Devising R&D strategy for commercialization

Source: http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html

Case of CRISPR - “Biotech Trial of the Century”

Crispr (clustered regularly interspaced short palindromic repeats) is a revolutionary **genome-editing technique**

Potential benefits across human health, agriculture and industrial biotechnology

In 2015, Crispr technology moved beyond academia attracting **investment** from – **Novartis, AstraZeneca, Juno Therapeutics, Vertex Pharmaceuticals, Regeneron Pharmaceuticals, DuPont**

Patent battle casting a shadow over the technology’s future commercial potential:

- a) In 2012, Doudna and Charpentier (UC Berkeley) filed a **patent application**, followed seven months later by a separate patent application by Zhang (Broad Institute of Harvard and MIT).
- b) Despite being second to submit, Zhang was awarded the patent based on his **claimed invention date**.
- c) In February 2017, the US Patent Trial and Appeal Board ruled in favour of Broad Institute.

Source: <https://www.chemistryworld.com/business/crispr-goes-commercial/9359.article>

IP Due Diligence – Basic Elements

- **Parties** – ‘Seller/Licensors’ and ‘Buyer/Licensee’
- **Purposes** –
 - ✓ Determine value of IP concerned
 - ✓ Determine the contractual terms (e.g. warranties, indemnities, etc)
- **Process** – Requires three major actions:
 - ✓ Non-Disclosure (Confidentiality) Agreement
 - ✓ Memorandum of Understanding (MoU)
 - ✓ IP investigation procedure
- **Other considerations** –
 - ✓ Collecting and cataloguing of all the information
 - ✓ Assistance of IP attorney in performing an IP investigation
 - ✓ Due diligence should be proportionate to the value of IP

Common Questions/Concerns that Guide IP Investigation Process

Fields of IP investigation	Concerns/Questions
Contents and protection of IP	<ul style="list-style-type: none"> • What is the content of the IP in question? • Is the IP protected/protectable? • Does the IP possess all the necessary requisites to be protected? • Can it be protected uniformly in all the countries of interest?
IP rights	<ul style="list-style-type: none"> • Does any third party, including employees or other personnel, have rights to this IP asset? • Are there any agreements/contracts with third parties that may affect its free use and what risks do they imply?
Infringement	<ul style="list-style-type: none"> • Does the IP asset infringe any third parties' IP rights? • Are there any competing/blocking IP rights?
Commercial application	<ul style="list-style-type: none"> • Has the IP asset in question been “field tested” to ensure that the related technology works? • What are the expected market applications of the technology? • How much investment does the technology require to be brought to the market? • Are there any competing technologies?

Assessment of IP Assets – Issues and Actions

Issues	Actions needed
Validity of IPR	➤ Information on the validity of the IPR concerned could be provided by showing the relevant register
Controversies	➤ Information on any controversies surrounding the technology which might have occurred during the IP protection procedure, e.g. checking the novelty, inventive step, sufficiency of description of the subject matter of a patent, etc)
Legal status	➤ Check the legal terms under which employees' inventions have been made
Contractual situation	➤ Check the contractual situation related to the technology concerned with third parties, i.e assignments and licensing agreements, terms and conditions, authorization to grant sub-licenses, scope of granted licenses, etc.

Strategic Thinking Before Drafting Agreements

- Technology Transfer agreements should be either drafted or thoroughly reviewed by an IP attorney
- Stop thinking in terms of a template for drafting a license
- Start thinking in terms of appropriate clauses for a license
- Most attorneys start with clauses from other agreements and modify them to fit the particular situation and desires of the parties.

Drafting and Negotiation

- The negotiating team should prepare a preliminary draft known as **'Heads of Agreement'**
- This document should have a **summary of the key commercial as well as technical details** to be negotiated and agreed upon
- This document acts a **guide during the negotiation process** and facilitates clarity and progress in the overall negotiations
- As a first stage of the negotiation, the **transferor makes a presentation** of the technology and **submits a draft outlining the terms of the agreement.**
- **Clarifications are sought** on this draft and as the negotiation progresses the **draft may be updated many times.**

Main Types of TT Agreements

- **Sale or assignment of IP rights** – No restriction in time/any other conditions
- **License contract/agreement** – Rights restricted to specific country/duration
- **Know-how agreement** –
 - Tangible form (Documents, Photographs, Blueprints,)
 - Intangible form (Explaining a process, Technical training)
- **Mergers & Acquisitions** – Combine technology, technical personnel, other assets
- **Franchise** – Combines know-how, technical & managerial services of one entity with the investment of another entity
- **Acquisition of equipment/capital goods** – Sale, Purchase, Import
- **Consultancy arrangements** – Management/Technical advisory services
- **Joint Venture (JV) agreements** – Equity JV (separate legal entity); Contractual JV (where separate entity not possible)
- **Turn-key project** – Combines range of services (Planning, Construction and Operation)

Key Provisions of TT Agreements

- **Subject matter** – Patents, Confidential information, Technical know-how, trade secrets
- **Product/service definition** – Provides exact description of the product or service for which technology is being transferred
- **Confidentiality** – Obligation to maintain confidentiality; Extent of permissible disclosure; Remedy for breach of confidentiality
- **Extent of rights** – Scope of license (e.g. exclusive, sole, non-exclusive)
Geographical territory for which the license is granted; Term of duration

General Considerations of TT Agreements

Representations and warranties - Statements or assurances about a matter or position relevant to the licensing agreement (Ex. Licensor owns the technology, has right/authority to grant license; licensed material is original; licensed IP is valid, not infringed by 3rd party, etc)

Indemnity - Licensor agrees to indemnify (reimburse/compensate) the licensee for infringement of any rights

Licensor's obligations – Guarantee of product quality; Allowing use of IP, Providing technical assistance, Training; Buy-back of product if any

Licensee's obligations – Making payment to licensor; Maintaining confidentiality; Exploiting technology to maximum benefit; Reporting production details; etc

General Considerations

(Cont'd)

Amendment – Entities need to agree in writing that the TT agreement may be amended whenever necessary

Assignment or other transfer - Whether agreement can be assigned/transferred to any subsidiary or group company of any of the entities, successors or assignees

Other general clauses: Preconditions , Anti-competitive practice, Government regulations, Expiration and termination, Consequences of termination, Applicable law, Disputes, Arbitration, etc

Commercial/Financial Considerations

- **Timing of commercial production** is critical for payment of royalties based on sales of manufactured goods and products
- **'Inspection and information'** provision allows the licensor to inspect any information required from the licensee with regard to production and sales records
- **Payment options** – Lump sums or Royalties
- **Royalty variables** (e.g. reduction of royalty rate as the volume increases or time passes)
- **Inflation** could be effectively addressed when royalty rate is expressed as percentage of sales
- **Financial administration** – obligations on the licensee to keep accounts and records and to report the results to licensor and pay the consequent royalties
- **Infringement issues**

TT Agreements at different stages of commercialization



<http://www.wipo.int/amc/en/center/specific-sectors/rd/>

Model TT Agreements?

- **No universal or standard format** for all types of technology transfer
- **Vary according to specific requirements with appropriate clauses**
- Examples of TT agreements suitable for different TT situations
 - ✓ Non-disclosure agreement
 - ✓ IP sale or assignment agreement
 - ✓ Agreement for licensing of know-how
 - ✓ Model agreements for IP rights in joint ventures
 - ✓ Sale and purchase of equipment
 - ✓ Consultancy agreement
 - ✓ Licensing of trade mark
 - ✓ Invention Disclosure Form
 - ✓ Model agreements for collaborative and sponsored research

TT Agreement Checklist

- Checklist of necessary **considerations and steps** before signing the TT agreement:
 - ✓ Preliminary considerations – Analyze potential of partnership/alliance
 - ✓ Assessment of IP assets
 - ✓ Assessment of other assets
 - ✓ Legal framework for technology transfer
- Checklist for the **structure** of TT agreement:
 - ✓ Preliminary requirements – General and financial clauses
 - ✓ Subject matter of the license
 - ✓ Miscellaneous provisions

TT Agreement- Final Considerations

The parties willing to sign a TT agreement among themselves should consider the following issues before entering into the final contract:

- They should **collect and catalogue all the information** that is likely to be of interest for the potential partner, in an organized and easily retrievable way;
- It is advisable to take the **assistance of an IP attorney** in performing an IP investigation; and
- **Due diligence should be proportionate to the value of the deal.**

TT Agreement- Policy Implications

- Subject to prevailing national laws and regulations
- Determine the extent of financial, material, services and technology transfer
- Compliance with standard conditions, stipulations and limitations
- Standard conditions attached to approvals for TT in FDI
- The process of approval may vary depending on the type of agreements

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Thank you

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