

# International Workshop on Intellectual Property Management and Technology Licensing

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## Preparing Technology Transfer and Business Partnership Agreements – key considerations

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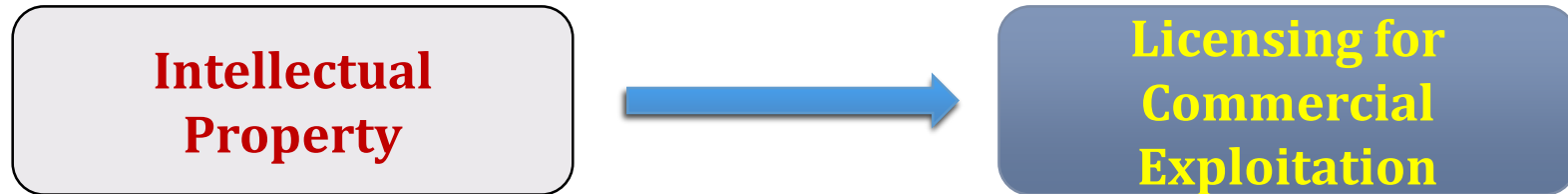
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# Outline

- Patents at the core of business
- Main types & benefits of licensing agreements
- IP due diligence and investigation
- Drafting of licensing agreements - key considerations

# Intellectual Property at the Core of Business



Inventions need to fulfil 3 basic requirements of patentability –  
**Novelty; Inventive step (non-obviousness); Industrial application or utility**

To be borne in mind while:

- (a) Drafting patent applications and license agreements
- (b) Devising R&D strategy for commercialization

Source: [http://www.wipo.int/sme/en/documents/patents\\_biotech\\_fulltext.html](http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html)

# In the Shoes of Investors

- Ventures with new patents could be **capital-intensive**; investments have **long payback period**.
- **Clear ownership of IP**
- **Centrality of patents** in the industry
- Conduct thorough **due diligence** prior to investing
- **Freedom to operate** without any IP infringement.

Source: [http://www.wipo.int/sme/en/documents/patents\\_biotech\\_fulltext.html](http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html)

# Case of CRISPR – A Lesson for the Industry

**Crispr** is a revolutionary **genome-editing technique** - Health, Agriculture, Industrial biotechnology

**Investment** – **Novartis, AstraZeneca, Juno Therapeutics, Vertex Pharmaceuticals, Regeneron Pharmaceuticals, DuPont**

**Patent battle** between **Broad Institute** of Harvard & MIT, and **UC Berkeley**

(a) UC Berkeley - First to file patent application (2012)

(B) Despite being second to submit (7 months later), Broad Institute was awarded the patent based on the basis of **claimed invention date**.

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

## Stages of Technology Transfer

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

# Agreements vary with Business interests

- **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 agreements** – To procure management/technical advisory services
- **Joint Venture (JV) agreements** – Equity JV (separate legal entity); Contractual JV (where separate entity is not possible)
- **Turn-key project** – Combines range of services (Planning, Construction and Operation)

# Agreements at different stages of commercialization



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



# Benefits of Licensing Agreements

- **Contractual agreements are** enforceable under law
- **Address conflicts** between parties by referring to the respective clauses
- **Provide flexibility of coverage** over one or more types of IP
- **Address trans-national issues**
- **Promote long term business relationship**

# IP Protection in Biotechnology

Patents	<ul style="list-style-type: none"><li>• Isolated polynucleic acids, peptides and polypeptides, enzymes, microorganisms, viruses, vectors, antibodies, probes, vaccines, compositions, expression systems, cell lines, plants, seeds, transgenic organisms, methods for preparation or use of the above;</li><li>• medical devices</li></ul>
Trade marks	<ul style="list-style-type: none"><li>• Words/name, computer icons, graphical designs, multimedia elements or use of the above;</li><li>• medical devices</li></ul>
Registered designs	<ul style="list-style-type: none"><li>• Medical devices, biochemical, biophysical or bio-electrochemical apparatus</li></ul>
Trade secrets / know-how	<ul style="list-style-type: none"><li>• Laboratory notebooks, design workbooks, customer information, documented internal processes, "data exclusivity" on clinical data generated for therapeutic approval</li></ul>
Plant breeders' or plant variety rights	<ul style="list-style-type: none"><li>• Plant varieties, propagating and harvesting material from plant varieties</li></ul>
Domain names	<ul style="list-style-type: none"><li>• Web addresses</li></ul>

Source: [https://www.iprhelphdesk.eu/sites/default/files/newsdocuments/IP\\_in\\_Biotechnology.pdf](https://www.iprhelphdesk.eu/sites/default/files/newsdocuments/IP_in_Biotechnology.pdf)

# IP Due Diligence – Basic Elements

## To determine

- ✓ Value of IP
- ✓ Contractual terms

## Process

- ✓ Non-Disclosure (Confidentiality) Agreement
- ✓ Memorandum of Understanding (MoU)
- ✓ Materials Transfer Agreement and Evaluation Agreement
- ✓ Inter Institutional Agreement
- ✓ **IP investigation**

## IP Due Diligence – key considerations

- ✓ Assistance of IP attorney in performing an IP investigation
- ✓ IP due diligence should be performed at the beginning of negotiation & drafting of license agreement
- ✓ Collect and catalogue of all the information related to IP
- ✓ The collected information is used for negotiation and drafting of licensing agreement

# Common Questions during IP Investigation

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

# Drafting Licensing Agreements – key considerations

- Should be either **drafted or reviewed by an IP attorney**
- **Stop thinking in terms of a template** to draft a license
- **Start thinking in terms of appropriate clauses** for a license
- May **start with clauses from other agreements and modify them** to fit the particular situation and desires of the parties

# Drafting & Negotiation

- **Drafting & Negotiation** proceed simultaneously
- Prepare a preliminary draft '**Heads of Agreement**' – Summary of key commercial & technical details to be negotiated
- The document acts as a **guide during negotiation**
- As negotiation proceeds the **draft gets updated many times**

## Concluding Remarks

- **Strength & centrality of patents** are key to commercial success
- **Type & structure** of licensing agreements would vary as per specific requirements and business interests of parties
- **IP due diligence** is key to investment decisions and a necessary prerequisite for negotiation and drafting
- Drafting and negotiation should **proceed simultaneously**
- Start thinking in terms of **appropriate clauses** rather than a template for drafting



# Thank you

## For more information, contact

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