

LICENSING & TECHNOLOGY TRANSFER

Licensing

Q1. What is licensing?

A license is a legal agreement by which the owner of an invention (licensor) grants rights to the licensee to make, use, and/or sell the invention within the framework of license agreement. Any entity that aims to manufacture and market a patented product needs a license from the licensor.

Q2. How do you license an invention?

Licensing, in simple terms, is the buying or renting of the rights to intellectual property (the invention) with the intent to produce and market, typically on commercial terms. . The inventor who licenses his or her invention receives a fee for the invention being licensed. Such a payment could be a one-time payment (lumpsum payment) and/or percentage of revenue generated as royalty. The Licensing Agreement therefore paves the way for an invention into a marketable product. The process of licensing of invention varies from organization to organization but is typically negotiated between teams from licensor and the licensee. The major parameters in licensing include:

- Exclusivity of the licence
- Lumpsum upfront payment
- Rate and mode of payment of royalty.
- Territory for the licensing agreement
- Liability issues

Q3. What issues are to be considered before collaborating with a company?

The inventor must enter into a properly drafted Non Disclosure Agreement (NDA) with the company before initiating discussions to ensure that the invention is protected from unfair exploitation. If the collaborator and/or the company seek material for testing and evaluation, a properly drafted Material Transfer Agreement (MTA) must be signed or a commercial evaluation license or an internal commercial use license may be signed.

Q4. What is a Material Transfer Agreement?

Tangible research materials created by researchers must be protected through a specific legal agreement. Such agreements are called Material Transfer Agreements and are useful for commercial development or even for further R&D. It is important to contact the IPR or Technology Transfer Units prior to receiving or sending out any research materials to enable protection of IPR from unfair exploitation.

Q5. What is a Confidential Disclosure Agreement?

The transfer of proprietary information, even in a casual conversation, could legally be considered a public disclosure and hence loses protection. In the worst case scenario, such a disclosure could allow the individual or a company, to whom this information was disclosed to use or transmit to others your confidential information, thus placing it in the public domain. Further, this would preclude the possibility of obtaining intellectual property protection and therefore may lose commercial value of the invention. Therefore a legal agreement between the transferor of proprietary information (such as a researcher) to another entity (such as a corporate representative of a researcher) is necessary. Such a legal document for the protection of proprietary information is called a Confidential Disclosure Agreement or Non-Disclosure Agreement.

Q6. What is a Commercial Evaluation license?

Commercial Evaluation License typically grants a non-exclusive right of limited duration to make and use an invention for the purpose of evaluating its commercial potential. The license does not grant the right to sell or otherwise distribute the invention. Companies are required to obtain a commercial patent license for further use and/or development of the invention.

Q7. What is an Internal Commercial Use license?

Internal Commercial Use License, grants the non-exclusive right to the licensee to make and use the invention as a tool in the Research & Development and/ or production activities. These licenses do not grant the right to sell or otherwise distribute the invention, but allow the licensee to use the invention.

Q8. What is non-exclusive and exclusive patent license?

Both non-exclusive and exclusive Patent Licenses allow a company to commercialize the invention as per the licensing agreement. An exclusive license limits the use of the invention to a single entity barring others from use. Non-exclusive license, on the other hand, is given to multiple licensees to different entities for commercial exploitation.

Q9. What are the advantages of licensing a technology?

Licensing an intellectual property will help:

- Ensuring commercialization of an invention
- Bring the product to market for public use.
- Generates revenue to the inventor(s) and the agency.

- Enhances the image of the organization as the product carries the details of the licensor.
- Helps the economy of the country.
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Q10. What is compulsory licensing?

Compulsory licensing is a system when a government allows a company to produce a patented product or utilize a patented process without the consent of the patent owner. It is well defined under the patent act of a country.

Q11. Does the Indian Law provide for compulsory licensing?

As per the Indian Law, a compulsory license can be sought after 3 years from the date of the grant of the patent on the following grounds:

- a. If the reasonable requirement of the public (domestic and foreign) need for the product have not been satisfied
- b. If the Patented Invention is not available to public at a reasonable price;
- c. If the Patented invention has not been worked in India.

Additionally, in the case of a national emergency and/or for preventing major disease epidemics, the Controller can permit compulsory licensing irrespective of the above three conditions. (For compulsory licensing under Paris convention, refer chapter VI; International Scenario of IP)

Q12. What are the different types of Compulsory licenses?

Compulsory licensing can be categorized based on the conditions required for its application. It is also defined in the Indian Patents Act, 1970 (as amended) under sections 84 for patent misuse, under section 92 for compulsory licensing in Public interest, under section 92 (A) for exports of pharmaceutical products and under section 91 for compulsory licensing for related patents.

Technology Transfer

Q1. What is technology transfer?

Technology transfer is the formal transfer of IP or other rights to any entity to use and commercialize new invention. Typically, transfer technology is done after protecting the IPR (viz., patents and copyrights) after a process of due diligence about the company and with some terms and conditions for licensing.

Q2. Why is technology transfer required?

An invention would be beneficial for the public if transferred successfully through technology transfer and marketed. In the health sector, tech transfer ensures availability of new and better products for public use. Technology transfer and commercialization of inventions provides monetary benefits to the inventors, agency supporting the inventions, the company and also the country.

Q3. What is the process of ‘technology transfer’?

Technology transfer is a process that recognizes the practical and commercial aspects of basic science research and discoveries and increases its outreach for the benefit of public and also encourages further innovation.

Technology Transfer/management also comprises evaluation and management of invention portfolios, patent prosecution, demonstration of knowhow, negotiating licensing agreements and periodic review of cooperative research agreements already in place. Part of the technology transfer process involves the prosecution of patents which is overseen by the National Patent and Trademark Office. Individuals with advanced degrees in the subject are needed to review and process patents in the relevant field such as a biomedical expert is needed to review and process patent of biotechnology.

Q4. What is the purpose of technology transfer?

Coordination, nurturing, and linkages are the basic function of technology transfer process. The coordination between technology users and developers as well as between researchers and manufacturers is an important element of technology transfer. During the coordination process access to relevant internal and external resources to individual projects and enterprises has to be enabled by participating parties.

The main ingredient for moving technology from a research laboratory to a company for manufacture and marketing is an environment that is supportive of entrepreneurship. This needs to be encouraged by providing guidance, counseling and resources to nurture the new technology.

For linking the various components of technology it is required to catalogue resources related to business enterprises and connecting would-be entrepreneurs/researchers and other technology developers to outside entities which can help in the manufacturing and marketing of products.

Q5. How is the status of technology graded?

In terms of technology transfer, technologies can be categorized as developing technologies, emerging technologies and established technologies.

Developing technology is an innovative technology that currently is undergoing bench-scale testing, in which a small version of the technology is tested in a laboratory.

Emerging Technology is a technology that has been field-tested but lacks a long history of full-scale use. Information about its cost and how well it works may be insufficient to support prediction of its performance under a wide variety of operating conditions.

Established Technology is a technology for which cost and performance information is readily available. Only when a technology has been used at many different sites and the results are fully documented, a technology can be considered as established.

Q6. What are the basic steps to be considered while transferring the technology?

Technology transfer activities include

- Evaluation/assessment of the invention.
- Protection of intellectual property relating to the technology.
- Finding the most suitable partner for licensing
- Licensing to that entity.
- Demonstration of the working of technology
- Assist in Pilot level and later large scale manufacturing.

Q7. What is Freedom to Operate (FTO)?

Before commercializing a product in a country or region, generally a Freedom to operate search is suggested to confirm that the IP/technology being licensed does not infringe IP technology of another party. A Freedom to operate is typically a professional and extensive search in the field of intellectual property (not restricted to patents only).

A freedom to operate opinion related to patents usually includes the findings on patent searches in relevant jurisdictions and their expiration dates.

If the searches result into presence of valid IP rights of others that are likely to be infringed, one can negotiate with those parties to license their IP to facilitate bringing out the intended product into the market. FTO also helps the avoidable legal action by others.

Q8. How is the commercial potential of a technology assessed?

Commercialization potential is most significant aspect of an effective technology transfer. Establishing a technology's prospects for commercial success depends largely on five factors:

1. **Demand of the technology:** Technology must be new or improved version of the existing technology i.e. if it is simpler, cost effective or more efficacious.
2. **Technical Development:** The time, materials, and personnel needed to reduce the technology to practice and protect rights to the resulting product.
3. **Regulatory Clearance:** The testing needed to demonstrate the product's utility and safety, to meet regulatory requirements of the country in order to minimize or manage associated risks.
4. **Manufacturing Requirements:** Manpower, Facilities, and equipments needed to make the product.
5. **Market Development:** Plan for successful marketing, created by assessing perceived need for the product, size of potential market, expected sales, advantages over competing products, and the cost of promoting the product.
6. **Financial Feasibility:** The development cost, production cost, operating expenses in relation to sales potential, net profit, potential liabilities, and return on investment.

Q9.Does the sale of a technology constitute technology transfer?

Technology transfer is not about selling some hardware to a client who is then left with the task of using it as he/she deems fit. Technology transfer is the process of imparting of knowledge, skills and methodologies involved in the whole production cycle. Technology transfer is a system that encompasses the social and economic fabric of a country. Where technology has been effectively transferred, there should be a visible change - from the person to the production system as well as compatibility with the needs, in the institutional framework, skills, training, financial capacity, promotion, and active support of endogenous capacity and appreciation of the natural environment of the recipient country. Technology transfer also has to do with disseminating information on the technologies themselves.

Q10.How do academic institutions measure success in technology transfer?

The success in technology transfer can be categorized as “**Numerical**” and “**Non-numerical**”. Under the numerical measures the “early numerical measures” include the number of patents filed, license agreements executed and new companies formed. “Late numerical measures” include revenues from license fees, royalties and cash from equity investments paid to the academic institutions and the numbers of products successfully introduced to the market. The “Non-numerical” includes - university's ability to retain entrepreneurial faculty, attract outstanding graduate students, contribute to the institutional reputation for innovation, augment its research program through interaction with the private sector and enhance its reputation for providing highly trained students for the industrial work force.

Success is also demonstrated by the impact the products have on the lives of general public.

Q11.What are the benefits of technology transfer efforts made by R&D institutes?

The licensing of innovations by Academic institutes, R&D institutes, and hospitals may be collectively termed as “Academic technology transfer”, such a transfer may add substantial amount of money to the Indian economy and increased employment opportunities. Further, it contributes to the spawning of new businesses, creating new industries and opening new markets. Most importantly, successful tech transfer leads to new products and services that improve our quality of life, from new cancer treatments to faster gadgets environmental friendly devices etc. that make the way we live and work better.