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Licensing In Biotechnology

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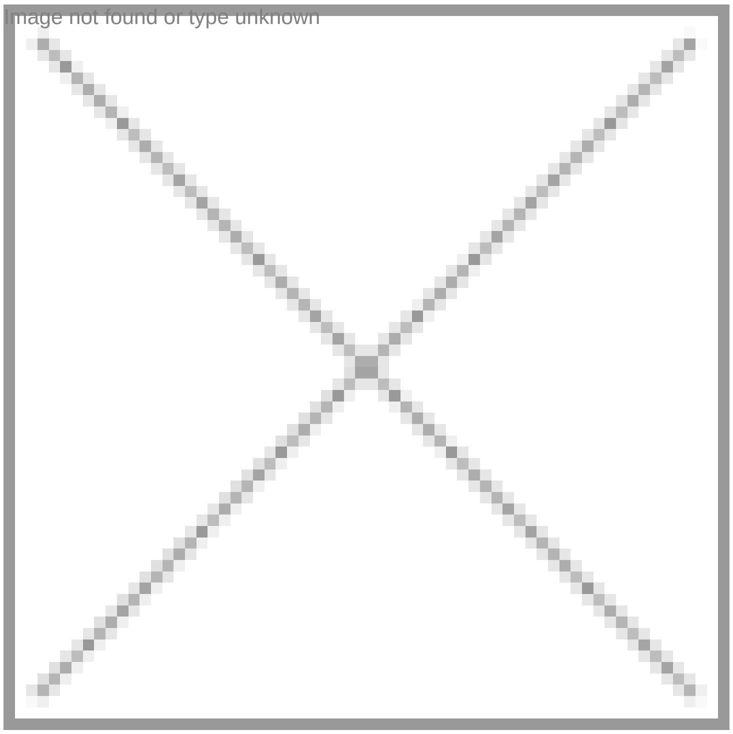

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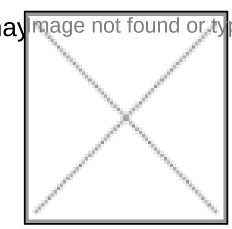

The journey of an invention from lab to the market is a long and winding one with many hurdles and may pass through bridges such as licensing and assignment before its end.

1. Strategy

There are at least two common methods of exploiting a technologyâ€”license and assignment.

A patent enables its owner to stop the public from using, making or manufacturing the invention for which the patent has been granted. It includes within its sweep the right to mortgage, license or assign one's interest in the patent to another. An assignment in effect is the complete transfer of one's rights and interest in a patent to another. After such assignment, the patent owner divests himself of ownership and the purchaser is the owner thereof.

A license under Indian law is a right that is given to a person to do something, which otherwise is unauthorized and illegal. Upon grant of a license, the patent owner does not divest himself of ownership in the patent or the technology in question and continues to exercise all rights as owner therein. In practice however, a license extends beyond the patent to include the technical know how as well.

Assignment type of transaction is effected in cases wherein the patent owner is really convinced that he has no use for the technology or that he cannot in any manner exploit it. It occurs when a company is taken over by another or at the time of its winding up. A license type transaction is chosen with a view to retain hold of proprietary rights of the technology as well as earn reward for the efforts made in developing the technology.

2. Overall structure of transaction

Prior to execution of a license or assignment, it is important to ascertain what exactly is required to be licensed or transferred. Consider a situation wherein one had patent rights to a novel medium for culturing cell lines and a method for developing cell lines using the medium and the purchaser/licensee uses only a specific cell line, it is sufficient to license the culture medium and there is no need to license the patent relating to the use of the medium.

Similarly, where a broad patent covers a diagnostic tool useful for probing several diseases, a part of the patent relating to the use of the tool for diagnosis of a specific disease may be provided.

In cases that involve technology that is yet being developed, like collaboration for identification of new chemical entities from a plant extract, it is advisable to set out specifically the scope of the project in a separate schedule as it avoids a lot of confusion when the agreement is subject to post-mortem after 10 years.

Often parties prefer to set out in this clause the obligations of each party in the contract. The milestones to be achieved are also set out making it easy for future reference. For example, where a project relates to identification of proteins useful as drug targets and raw material is to be prepared and supplied by different parties, it is so set out in the contract with approximate time lines so as to keep the project on track.

3. Licensed Products

Apart from defining the scope of license, it is important to define the product(s) that are licensed. It is important to define the licensed product so as to limit the use by the licensee, of products that do not fall within the definition. As an example, if the licensed product is a cell line, the licensor may, by appropriate definition, restrict use of materials other than the actual cell line that has been licensed and thus prevent the licensee from preparing and using derivatives or progenies of the licensed cell line.

Improvements that make the licensed product more efficient are usually kept out of the definition of licensed products. They may be offered to the licensee for an additional fee.

In some cases, improvements may be made by the licensee. In such a case the parties may agree that the improvements may be licensed free of cost to each other or offer the right of first refusal to the other or license the improvement for a concessional fee.

4. Material transfer

Where the license relates to a cell line or any similar biological material, the fact that material has been provided to the licensee must be stated with an acknowledgement thereof from the licensee. The licensee would need to insist that the product licensed is fit for the purpose licensed.

5. Consideration: product/services/technical know how

Monetary compensation is the most direct form of reward to an inventor. And it is often a bone of contention in almost every transaction.

- In a transaction like an assignment wherein the patent owner divests all his rights and interest in the patent once and for all in favor of the assignee, the payment is usually as lump sum for the technology and the patents assigned.
- A license on the other hand, may involve a combination of lump-sum payment and royalties or just work around royalties.
- Milestone payments track the timelines set by the parties, rewards the licensor for value of the invention, the value of which was unproven at the time of license. A license relating to an expression system could involve payment of a fee at each stage of scale up right from laboratory to pilot plant to clinical trials. Sometimes, parties agree to pay a fee for

every one thousand assays, such methods often prove to be cumbersome and difficult to police.

- The fee structure varies depending on scope of license, age of technology, market demand, profit margin, proprietary position of the licensor and strength of the technology.
- Yearly or quarterly fee are the common yardsticks for royalty payment.
- Setting a royalty rate for a product may be very difficult especially in case of biotechnology products, because technology is often licensed at a nascent stage when the form of the final product may not be known. Following are some common strategies followed in this area, although they may not be treated as thumb rule:
- Lump sum payment for initial stages followed by royalty payment on/after the launch of the final product.
- If final product is known, set a modest base rate that is scaled up depending on the success of the product
- Calculate royalty on every piece of the licensed product sold in the market or on net sales in a specific territory or worldwide.

6. Intellectual Property Rights

Very often, parties provide that all intellectual property rights in the technology transferred which may be by way of patents, trademarks, copyrights or trade secrets that vest with the licensor are also being licensed to the licensee. Without this clause, the licensee may have to negotiate with the licensor separate terms for use of these rights. For instance, if a screening assay is licensed together with the software that identifies various sequences of a particular type, one may not be able to copy or modify it, if the licensee had no rights to the software. The clause must define and include confidentiality obligations of either parties.

In India, any interest created in a patent must be registered with the Patent Office, which includes a license. Hence, the licensor and licensee may have to take steps in this regard.

Parties also need to negotiate as to who is to assume responsibility for maintenance of IP rights and for enforcement thereof. If the license granted is exclusive, it is the duty of the licensee to take action against infringements or at least bring it to the notice of the licensor.

7. Indemnities and Warranties

In any technology transfer, the licensee would be within his rights to ask for at least the following assurances from the licensor:

- Encumbrance free technology
- The technology being licensed is novel and does not infringe the intellectual property rights of a third party
- The licensor has the right to enter into this contract (and has not granted licenses to other parties).

A licensor may in turn limit these assurances to the specific technology licensed and not any appurtenant technology.

Product liability is an issue that must be negotiated depending on the level of participation by the licensee in market launch of the product. Perhaps, it is here that insurance covers assist the licensor. In India, the concept of patent insurances is still at a very nascent stage.

8. Exclusivity

Licenses granted may be exclusive i.e. limited to a single party or to several parties. The license may be limited to a specific territory or worldwide. Exclusivity is usually with respect to a party. Parties do make arrangements such that the licensor retains the home territory and licenses out the rest of the territories thereby enabling the licensor to freely exploit the technology at least within his own home territory. The only limitation of a worldwide license is that it could limit the freedom of the licensor in improving the technology and this is often the case when rights are assigned. An important issue to be negotiated may be whether a licensee is entitled to sub-license the rights acquired. It is often practical to do so if the technology has far reaching applications.

9. Termination and Miscellaneous clauses

Structuring the end of the transaction is as important as the beginning. Key questions that this clause must answer:

- Which obligations would survive termination?
- What about products already in market?
- Rights of third parties, if third party interests such as sub-licenses have been created
- Rights and duties of parties at the time of termination
- Whether non-solicitation covenants are required?
- Arbitration and jurisdiction

Conclusion

There is no one-fit all master agreement that would fit all types of transactions because with time we realize each transaction is one of its kind. The goal is to achieve a good agreement, which clearly reflects the intention of the parties and chalks out the options they have in mind. Apart from consistency and clarity, overly limiting clauses or those that are lop-sided should be clearly avoided to create a win-win situation for both parties.

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K & S Partners

K&S Partners is a full-fledged intellectual property law firm with offices in New Delhi and Bangalore. It specializes in the entire gamut of intellectual property laws, protection and enforcement.