Kirk-Othmer Encyclopedia of Chemical Technology.

LICENSING

A license is an agreement between two or more parties which conveys certain intellectual property rights (eg, patent, copyright, trademark, or know-how) from the licensor (the holder or owner of the intellectual property rights) to the licensee (the recipient of the intellectual property rights). For the sake of simplicity, herein a licensor (the entity which is licensing-out) and licensee (the entity which is licensing-in) are assumed to be companies; however, an individual, the government, or a nonprofit entity such as a university may also be a licensor or licensee. Because a license is a legal contract or agreement between two or more parties, a discussion about licenses could emphasize the legal aspects of the terms and conditions; however, a license is more often entered into because of business reasons, hence this article focuses more on the business aspects of licensing.

1. Reasons for Licensing

In any contractual arrangement, each party has a particular set of reasons to enter into the agreement. In a licensing arrangement, the licensor holds rights to certain intellectual property that may be of value; the licensee would like access to those property rights in order to make, use, or sell products covered by such intellectual property rights.

1.1. Licensor's Perspective

Recognizing that its intellectual property has value, the owner may want to allow others to exploit the intellectual property through a licensing arrangement for a variety of reasons. (*1*) The licensor may not wish to take on the financial and resource risk of developing the product itself, knowing that it takes more money and time than the company is willing to invest. (*2*) Even if the licensor is interested in developing new products, the company may not have enough resources or expertise to develop the product itself. (*3*) The licensor may not want to incur the liability that would be associated with the product, eg, product liability for a vaccine. (*4*) The licensor does not know or understand the marketplace involved in the particular intellectual property and wishes to focus on those areas it knows best. (*5*) The licensor wishes to generate royalty income. (*6*) Although the patentee or copyright holder is often in a strong position with respect to the enforcement of intellectual property rights, the licensor wishes to avoid potential litigation by granting a license to a company which is using the licensor's intellectual property. (*7*) The licensor is selling a product protected by certain intellectual property rights, but would like to allow a second source of the product to come into being, and therefore grants a license to another company. Potential licensors may not want to grant licenses, because the company wants to keep all of the profits or wants to prevent competitors from entering the marketplace. Ultimately, the decision whether or not to license-out should be part of a strategic business decision.

1.2. Licensee's Perspective

A potential licensee may be interested in entering into a license agreement for a number of reasons. (*1*) The licensee would like the opportunity to augment its own research and development efforts by acquiring technology from other parties through licensing. (*2*) The licensee would like to acquire new ideas which fall into the licensee's research or business areas of expertise. (*3*) The licensee wants to avoid litigation. (*4*) There is often a window of opportunity via licensing to enter new markets, develop new products, etc, so as to be the first in the marketplace.

On the other hand, the technical and market risk involved in licensing technology, the difficulty in assessing the value of a particular intellectual property, and the fact that the technology is developed outside the license company often makes licensing less than desirable. Like licensing-out, licensing-in should be a strategic business decision.

1.3. Overall Perspective

For both parties, some of the factors which affect the decision to license-out or license-in within a strategic business plan might include (*1*) an assessment of competing products, (*2*) an assessment of alternative approaches, (*3*) an assessment of the real and perceived features, advantages, and benefits of the technology, (*4*) projections of market potential, and (*5*) the life span of the product. In addition, the question should be asked, "Is the technology evolutionary?" in which case a potential licensee would have to decide whether or not the technology is worth the investment, or is it "revolutionary," in which case the potential licensee might not want to "miss the revolution." In all cases, both the licensee and licensor must see a benefit from the license agreement in order for the business relationship to be successful.

2. Components of a License Agreement

Every license agreement is a negotiated contract between parties, and therefore there are no hard-and-fast rules as to what is required in a license agreement. Since every provision is negotiable, the license agreement should be viewed in its entirety, rather than as component parts. Nevertheless, for purposes of illustration, select component parts will be discussed.

2.1. Diligence

Although the financial terms of a license agreement generally receive the most attention, "diligence" provisions, ie, those provisions which specify the obligations of the licensee to develop the technology diligently, are often more important. The diligence provisions should set forth the expectations and understanding of both parties as to the developmental time frame and milestones to be met by the licensee. These provisions are important because they allow both parties to know if the intent of the license is being met. It gives the licensor a means of measuring the progress of the licensee in bringing the technology to the marketplace, and it can allow for termination if the milestones have not been met. In most licensing arrangements, the issue which should be of greatest concern to a licensor is that the licensee is diligently developing the technology. Otherwise, the licensor will not reap the potential benefits from having licensed the technology.

An example of a diligence provision might be as follows:

> As an inducement to Licensor to enter into this Agreement, Licensee agrees to use all reasonable efforts and diligence to proceed with the development, manufacture, and sale of the Licensed Product and to diligently develop markets for the Licensed Product. Unless Licensee has a Licensed

Product available for commercial sale prior to ___, Licensee agrees that Licensor may terminate this Agreement. In addition, Licensee agrees: (*1*) to have a prototype developed by ___; (*2*) to have tested the prototype in ___; (*3*) to have developed a marketing plan; (*4*) to have sold *xxx* units by ___; and (*5*) to have generated $___ in sales by ___.

2.2. Financial Terms

2.2.1. Royalty-Free Licenses

Although most licenses involve a financial transaction, it should be noted that royalty-free licenses can be and often are granted, allowing a licensee to practice an invention or obtain rights under copyrights without making compensation. Royalty-free licenses allow the licensor to retain ownership or other control over the intellectual property but do not provide a financial return to the intellectual property owner.

2.2.2. Royalty-Bearing Licenses

A royalty-bearing license presumes a financial exchange between the parties, ie, the licensor grants certain intellectual property rights to the licensee for monetary consideration. Some royalty-bearing licenses are known as fully paid, in that once the payment is made no further payment is expected or due. Other royalty-bearing licenses specify payments throughout the term of the agreement. For licenses requiring payments throughout the term of the agreement, payments may include a license issue fee or upfront payment, annual payments, milestone payments, and earned royalties based on sales.

2.2.2.1. License issue fees. also known as upfront payments, are often but not always required from licensees as a gesture of good faith and serious intention by the licensee to develop the technology. It can be viewed as a down payment based on the perceived or actual value of the technology. Licensees generally prefer to pay as little as possible prior to sales; licensors prefer to generate income as soon as possible. The licensor and licensee can structure the financial terms such that upfront payment can be credited, ie, prepaid, against earned royalties, thereby meeting the desire of the licensor to obtain more cash upfront but also meeting the desire of the licensee to leverage the upfront payment against future royalty obligations.

2.2.2.2. Annual payments. are often viewed as a financial diligence provision or as a fee for maintaining the license. If a licensee must make a yearly payment, then the licensee will make a considered decision as to whether or not it is still interested in developing the technology. Some licensors prefer to have a greater time period, eg, two to three years, between payments, with more significant payments due at the end of the period. The risk for the licensor, however, is that if during the no-payment period the licensee has lost interest in the technology, the licensor has then also lost a time opportunity to find another licensee. Once the licensed product is being sold, annual maintenance payments often become minimum annual payments to reflect a minimum level of sales, eg, one-quarter of expected sales, acceptable to the licensor.

2.2.2.3. Milestone payments. are most often found in exclusive licenses and are generally linked to a licensee's meeting developmental milestones, such as a payment when the first prototype is made, when the first clinical trial is completed, when the product is approved for marketing, or even when the patent is issued. The milestone payment often reflects a sharing of the reduced developmental risk or increased value of the technology as the potential product moves through the developmental cycle. As the risk is reduced for the licensee, these milestone payments often increase monetarily. Milestone payments are also a means of enforcing diligence. A typical milestone/diligence clause might read, "Licensee agrees to have a product for sale by January 1, 1995 or pay Licensor $*x* in order to maintain the license."

2.2.2.4. Earned royalties. are typically a percentage of the net selling price of the licensed product, although they can be a set amount of money per sale, regardless of the sales price. If a licensee has successfully developed a licensed product, the licensor will realize the greatest return from the license through earned royalties. The earned royalty rate is determined by negotiation between the parties and can range from 0.1 to 20–30% or more, depending on the technology, stage of development, risk involved, value to the licensee or licensor, value added to the technology, etc. The earned royalty rate is also dependent on industry norms: earned royalties of 10–15% are not unusual for software programs, whereas earned royalties of 0.1–0.5% are not unusual in the semiconductor industry. In addition, the earned royalty rate should reflect the other financial considerations of the license agreement, for example, the licensee may be willing to pay significant upfront and milestone payments in exchange for lower earned royalty payments. Earned royalties can also be calculated as a percentage of profits, although this is a less common method of determining royalties.

2.3. Exclusivity and Nonexclusivity

Intellectual property can be licensed exclusively or nonexclusively, with many variations in between. Typically, an exclusive license gives the licensee an incentive to develop the intellectual property. Exclusivity is most valuable for technology that requires significant expense and long development time because it encourages the licensee to invest the risk capital to develop and market the invention. An exclusive patent license is only valuable if the patent has meaningful broad claims and is not easy to invent around. An exclusive license to copyrighted work is of limited value, since the copyright protects only the actual “original work fixed in a tangible medium” and others can express the same ideas in different ways.

An exclusive license is generally more valuable, and therefore more expensive, than a nonexclusive license because exclusivity provides an incentive and protection for the licensee’s investment in the technology. Licensors are limiting their future choices by granting an exclusive license, and therefore there is an opportunity cost for the licensor. Although most licensees prefer a worldwide life-of-the-patent exclusive license for all fields of use, exclusivity can be limited in time, geography (territory), field of use, application, etc. In granting an exclusive license, the licensor should be reasonably confident that the exclusive licensee can develop a marketable product; otherwise, the licensor may be losing an opportunity to exploit the invention. The licensor can grant the exclusive licensee the right to grant sublicenses to sublicensees, who in turn develop the technology.

From the perspective of the licensee, a nonexclusive license can be viewed as either a tax on the licensee’s use of the patent or insurance against a patent infringement lawsuit. The licensor may want to make the technology broadly available to many parties in order to allow many parties to better exploit the technology.

Varying degrees of exclusivity and nonexclusivity can be negotiated, eg, co-exclusive licenses, limited number of total licensees, etc.

Field of use restrictions are common in license agreements. For example, a licensor can limit the licensed field of use for the same compound to research reagents, diagnostic products, or therapeutic products. In this instance, a licensor can grant at least three exclusive field of use licenses for one technology.

2.4. Other Terms and Conditions

The license agreement should always have a specified term and include provisions for termination. Other standard provisions can be included to address such issues as reporting, infringement, indemnity/warranties, governing law, assignment, or notices.

3. Option Agreement and Right of First Refusal

An *option agreement* is a contract between two parties in which one party acquires the right (option) to acquire a license to specified intellectual property, usually within a given time period. Typically, an option agreement provides for an evaluation period and consideration for the option agreement at a lesser price than in a license agreement. Occasionally, the prospective license agreement is negotiated along with the option but can be postponed until the option is exercised.

An agreement which grants one party, the potential licensee, the right of first refusal is often interpreted to mean that the party has the right to match any other offer for the technology. If the party matches the offer, then the licensor must grant the license to the first, matching party. Potential licensees are able to use other parties to help gauge the value of the technology under the right of first refusal. For the licensor, this type of grant makes negotiations with other parties more difficult since the first party can always license the technology.

4. Types of Intellectual Property Licenses

4.1. Patent License

A patent license usually grants to the licensee the right to make, use, and sell products which otherwise would infringe a patent or pending patent application. Because a patent allows the patentee to exclude others from making, using, or selling the patented invention, a licensee is ensured immunity from a lawsuit by the patent holder.

4.2. Copyright License

In very simple terms, a copyright owner has the exclusive right to (*1*) reproduce, (*2*) prepare derivative works of, (*3*) distribute copies of, (*4*) perform, and (*5*) display the copyrighted work. A copyright license, therefore, grants to the licensee any or all of the rights associated with a copyright.

Software licenses are particular versions of a copyright license in which the holder of copyrighted software grants rights to another party to use the software. Shrink-wrap licenses are those which, when a package is opened, bind the opener of the package to use the software in the manner specified by the shrink-wrap.

4.3. Trademark Licenses

Certain drugs or chemicals may have a trademark associated with the compound and, as such, have a certain value. A trademark licensee has the right to use the trademark for the licensed products. Because a trademark reflects the source and quality of goods associated with the trademark, trademarked products and their licensees need to be monitored to ensure that the trademarked products meet the specifications of the licensor. Trademark licensors typically monitor licensed products by requiring the licensee to send representative samples to the licensor or allow the licensor to inspect the manufacturing facilities of the licensee. Trademark licenses also require that licensed products be properly marked to indicate the existence of the license (see Copyrights and trademarks).

4.4. Tangible Property Licenses and Material Transfer Agreements

Licenses which grant the licensee the right to use certain tangible property, such as cell lines and vectors, are very common in the biotechnology/pharmaceutical industry. These licenses are often used for nonpatented biological material and can be royalty-bearing and exclusive, as with other licenses. The termination clause in a tangible property license should include a provision for the return or destruction of the biological material if the license is terminated. In addition, there should be a provision that the licensee not distribute the material to others except with the written consent of the licensor.

Material transfer agreements are generally short letter agreements governing the exchange of biological materials between researchers. Typically, such material transfer agreements restrict the use of the biological material to a certain researcher and ask that the recipient of the material not distribute the material to others without prior consent. Material transfer agreements sometimes provide for the disposition of intellectual property rights which might arise from the use of the biological material.

5. Valuing Technology

The most commonly asked questions about licenses revolve around pricing and valuing the technology, eg, what is a reasonable royalty? There is no easy answer because many factors must be taken into consideration; some of these are discussed below. In the end, the value of the technology depends on what the licensee is willing to pay and what the licensor is willing to accept for the license. Licenses are usually a negotiated and unique agreement between two parties.

The value of the technology to be licensed depends on its potential technological and market competitive position; its features, advantages, and benefits; and whether the technology is evolutionary or revolutionary. Any evaluation of a technology should include an assessment of other competing products already being sold and who is selling a similar product. Another consideration is the cost or savings for each party. If there are viable alternative technologies or methods for obtaining the same or a similar end result, or if a company can easily invent around the technology, the license is less valuable to the licensee. Included in an evaluation should be market projections and an estimate of the life of the product; the larger the market and the longer the life, the more valuable the technology. A strong proprietary position also adds value to the technology. Lastly, there are often important intangible benefits which accrue to both parties and increase the perceived value of the technology.

Every industry has its own sense of what a reasonable royalty might be. Whereas earned royalties are usually based on net sales, a very rough rule of thumb is that an earned royalty reflects approximately 25% of profits earned on the particular technology. Minimum royalties are often based on one-fourth to one-third of a conservative projection of sales.

In pricing and packaging a license, the licensor must be very conscious of the perspective of the potential licensee. A successful licensor is prepared to make the license terms attractive to the licensee, emphasizing the features, advantages, and benefits of the technology and providing incentives for the licensee to take a license. The license is the basis for a long-term relationship between the licensor and licensee, and therefore both parties must feel that the agreement is fair and mutually beneficial.

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