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# Practitioner's Section

## Patent License Negotiation: Best Practices

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In all areas of the biotechnology and pharmaceutical industries, the licensing of intellectual property is in most cases an essential step in the translation of basic research into a commercial product. Negotiating IP licensing agreements and developing the terms of the business transaction involve evaluating numerous factors pertaining to the specific circumstances of the parties and the technology at issue. As the quality of the business relationship after licensing of the intellectual property is heavily influenced by the nature of the transaction, the negotiation process should be approached with great consideration. This article presents an overview of the negotiation process and makes suggestions for each stage.

Licensing of intellectual property is an inherent part of the biotechnology/pharmaceutical business. Very few technologies are commercialized without the licensing of intellectual property rights. Universities and emerging biotechnology companies often require the assistance of larger companies (so-called "big pharma") to fund and help navigate the regulatory approval process. Big pharma may look to emerging biotechnology companies for research and new marketable small and large molecules. Even products completely developed at in-house research facilities may require in-licensing of technology for the production of commercial quantities. The emergence of genetic testing to assist in the diagnosis and treatment of disease has resulted in analytical laboratories engaging in new rounds of patent licensing with the holders of intellectual property rights to the isolated genes.

In licensing, the negotiation process is a key determinant of the future business relationship between the stakeholders. In other words, "the quality of the final deal and the quality of the overall business relationship is governed by the quality of the negotiation." But what approach should a party take to negotiating patent licenses? And how are the interests of the licensor and licensee balanced to arrive at a deal? Our experience, and a review of relevant business and legal background, suggests the following as a possible "best practices" approach to patent or technology licensing negotiations.

### Preparing to negotiate

A key to any deal is for each party to have an understanding of what they want from the deal. Thus, effective negotiation begins with effective preparation. Effective preparation includes assembling the right team, preparing a heads of agreement, defining guidelines for the process, negotiating honestly, and drafting the contract.

**The Team.** In many negotiations both parties will have a deal team. The deal team will conduct due diligence and negotiate the license. A deal team will generally include a

 

Business Development Executive; a Scientific/Technical Expert; a Decision Maker; and a Licensing Attorney. The scientific and legal roles may be filled by multiple team members; for example, if the licensing attorney is not a patent attorney, a patent attorney will be needed on the deal team to understand the scope and nature of the patent rights and/or potential patent rights. The Business Development Executive is the person responsible for finding the deal and bringing the parties to the table. The Business Development Executive is often the leader of the deal team and responsible for keeping the negotiation process moving and ensuring the other team members fulfill their assigned tasks. In smaller biotechnology companies, the Business Development Executive role may be played by the company's CEO. Technology Transfer Professionals often play the Business Development role for Universities. The Scientific/Technical Expert(s) provide scientific and technological expertise to the deal team and conduct due diligence research relating to the technology at issue. The Decision Maker may or may not be the ultimate decision maker for a company, but should be someone who has authority to commit a party to particular deal terms. In an emerging biotechnology company, the Decision Maker is often the CEO. In a larger company, the Decision Maker may be a Business Executive with authority to bind the company within certain parameters. The Licensing Attorney, who is often an experienced patent attorney, is responsible for committing the terms of the agreement, and the desires of the parties, to writing. An experienced Licensing Attorney may also assist during negotiations by providing suggestions on alternative deal structures or terms when the parties reach an impasse. One or more members of the deal team are likely to be individuals that will be responsible for maintaining the relationship during the term of the license.

**Initial Team Meeting.** It is important that the deal team meet and reach an understanding of the business motivation for the deal and the responsibilities and role of each team member during the process (e.g., spokesperson, technology review, business evaluation, record keeping).

In preparing for the negotiation, the deal team should identify, assess and prioritize the interests of their client. The "client" may be, for example, a business unit in the case of a large corporation, the company in the case of an emerging biotechnology company, or the University in the case of a Technology Transfer Office. Client interests will be both tangible (e.g., longer terms, higher royalty rates, greater minimum guarantees) and intangible (e.g., building a trusting relationship, maximizing licensor's reputation, high quality product or service, creative commitment). While the tangible terms will structure the working relationship, they should not be achieved at the expense of intangible interests; otherwise the relationship itself may be compromised in the future.

The deal team should assess its own and the other party's position. To do so, steps could include 1) reviewing the strength and breadth of patent protection to determine the proprietary position offered by the patents, 2) conducting a right-to-use study on potential commercial products to determine the value of the patents and whether a license to any third party patent(s) are required, and 3) reviewing the developmental stage of the patented technology. For example, a small molecule pharmaceutical composition may be covered by species claims in a licensor's patent portfolio, but fall within the scope of a generic composition claim of a patent held by a third party. Thus, the value of the licensor's patents may be reduced by the need to license or otherwise deal with the third party patent. For the same small molecule pharmaceutical composition, the developmental stage will affect the amount of money a licensee will need to spend to bring the composition to market and the risk that the composition may fail to obtain FDA approval. Compositions that have shown efficacy through phase II clinical trials are generally worth more as the probability they will be approved is higher.

In addition, the team should evaluate and determine the marketing, technical, sales and services strengths of itself and the other party in the field of the patented technology. All of these factors are relevant to the amount of the licensing fee and royalty to be paid to the patent holder, in addition to other contract provisions, and help the parties to define the scope of the licensed technology and their competitiveness as potential licensing partners. Further, the team should carefully evaluate potential best alternatives to a negotiated agreement

(BATNAs) by determining, for example, the possibilities for alternative licenses, modifications or additions to existing contracts, delaying licensing, or bringing in additional partners or interests to raise capital and diffuse risk.

Before beginning talks with the other party, the deal team should determine what terms and conditions should be omitted from preliminary talks until formal negotiations begin. This is important because, until detailed negotiations begin, it is difficult to perceive the true value of any license and, thus, talks may unnecessarily breakdown due to discouragement over early positions that seem highly objectionable.

**The Term Sheet.** It is often helpful for parties to exchange a term sheet prior to the initial negotiation meeting. The term sheet typically covers the major issues in a potential deal in outline form, including: the licensed product or process; licensed territory; license fee and royalty; technical information and training required to develop and manufacture, sell and service the licensed product, and who will be responsible for same; sales and service support; degree of exclusivity, and duration of the license. The process of creating this document will help team members understand and focus on the overall objectives of the agreement and avoid unfavorable terms. Additionally, the document enables each party to understand their team's basic position from the start, avoiding potential misunderstandings as the negotiation proceeds.

**Deadlines.** Establishing preset deadlines for each of the major steps in the negotiation process is important because it forces the other party to reveal its true intentions and interests in the licensing agreement. Parties not committed to reaching an agreement will not meet deadline requirements, enabling the other party to cut its losses and look elsewhere for a potential licensing partner. Major steps in the negotiation process for which preset deadlines may be set include: the initial meeting, drafting the letter of understanding, executing the letter of understanding, meeting to review the draft agreement, revisions to the draft agreement, finalizing the licensing agreement and executing the licensing agreement.

The relative size of the parties will affect the ability of one party to hold the other to a deadline. In a situation where an emerging biotechnology or University is negotiating with a larger pharmaceutical/biotechnology company, the relative importance of the deal may make it the highest priority for the emerging biotechnology company or University, but only one among other priority items for the larger company. Thus, while the emerging biotechnology company may want and be able to meet aggressive deadlines, the larger pharmaceutical company may not be able to do so. Nevertheless, setting deadlines will allow an emerging biotechnology company or University to judge the other side's actual interest in a deal.

**The groundwork for open dialog.** In any negotiation, a nondisclosure agreement can provide security for both parties to maximize information transfer. Some key terms include license and scope, enforcement rights, the financial arrangement, additional patent prosecution and maintenance costs, ownership of improvements, liability, indemnification, and warranties and representations. A Joint Privilege Agreement will also be necessary if the parties intend to discuss legal opinions and avoid waiving the attorney-client privilege. Free sharing of information will also avoid costly diversions and evasive maneuvers.

Once a preliminary agreement is reached, the team should draft a letter of understanding and deliver it as soon as possible to the other party. The letter of understanding is a nonbinding document that outlines the general understanding and agreement between the parties. Its primary purpose is to aid in the drafting of the final agreement by fine tuning the broad terms and conditions elucidated during the negotiation and serve as a reminder to each party of their previously stipulated understandings. The document will typically include the following provisions: definition of licensed product; license grants; licensed territory; exclusivity; license fee and royalty; technical information and assistance; duration of license; and a provision expressly indicating hat the letter of understanding is a nonbinding legal instrument.

**Drafting the contract.** Commentators have suggested that the party drafting the contract is always in the more favorable position because that party will be in a position to ensure inclusion of desirable provisions and places the other party in the position of defending every request to modify the drafted agreement. In the experience of the authors, however, the non-drafting party

 

has not felt constrained to raise objections to an initial draft. Further, the non-drafting party may gain valuable insights into the other party's positions by making the other party "go first". Thus, there can be advantages to each position.

For the drafting party, including many minor provisions that can easily be given up is a good strategy, as this will permit the drafter to take a stronger position against objections to the more major provisions. By drafting the contract, a party is better able to evaluate any subsequent modifications or changes to the original draft and how such changes affect its primary goals. Drafting parties and non-drafting parties should approach negotiation over changes to the drafted contract differently: while the drafting party should relinquish minor claims early in order to take a stronger position on major provisions later on, the non-drafting party should attempt to review and revise major provisions first to avoid this.

The drafting party may be the licensor or the licensee. Universities often have "standard" license agreements that are used as first drafts. Emerging biotechnology companies with technology of interest to multiple suitors may be in a position to prepare initial drafts. When a deal is initiated by a licensee, they will often produce the first draft.

## The negotiation

The terms of a licensing contract reflect the allocation of risk between the parties of the potential future development and marketability of the patented technology. A licensor that has taken a molecule through one or more phases of a clinical trial, or has the financial resources to do so, will likely be in position to negotiate narrow licensing agreements that incentivize development and marketing of the technology and that enable additional licensing agreements with other licensees of different strengths that can compete in other markets. A licensor without these resources, financial or otherwise, will often be in a weaker bargaining position. Thus, emerging biotechnology companies generally try to generate at least phase I, and often phase IIA, prior to seeking to license technology.

Conversely, a licensee wants an exclusive license with the broadest license rights for the least amount of money with the requirement that it is paying for the rights and license scope that are required for its current and future possible business plans. Additionally, product liability and patent infringement indemnification are important to the licensee's security. To strongly support its negotiation position, a licensee should have a fully developed, detailed business plan that justifies the provisions it seeks by reasonably estimating profits and costs.

Ultimately, the market value of a patent is a measure of the potential sale of products or services that use the patented technology. To properly appraise the value of the patent it is thus necessary to determine the proprietary position (i.e., validity and enforceability) and competitiveness of the patent (e.g., minor improvement or pioneer break through, market size and dynamism); and the existence, or lack of existence, of third party patent rights related to the technology. In addition, the developmental stage of the technology and the scope of the license are risk factors that affect the amount of investment required to develop and market the technology and the competitiveness of the subsequent products or services. Lastly, the potential profitability of the licensing arrangement and the contributions of each party should be assessed. Therefore, all these elements must be considered by the parties when determining the terms of the agreement.

**Valuation approaches.** A business school/MBA approach to valuation often uses one of three methods: the cost method, the market method, and the income method. The value of the technology using the cost method is the cost of developing or purchasing the technology, though this does not reflect changes in the market or new information about the technology. Usually these "sunk costs" are irrelevant to the licensee, but they can factor in where the licensor can afford to develop the technology on its own and has no need to enter into a licensing agreement. Using the market method, the value is determined by evaluating the value assigned to comparable technology licensed recently, which requires determining what transactions are comparable and obtaining current, reliable data. The income method values technology by the total estimated annual returns (compare the estimated revenue or savings that the technology is likely to produce to the estimated cost or savings of using another source), which

reflects the bottom line of what the licensee can pay. Each of these methods, or a combination of these methods are often utilized by larger licensees. Emerging technology companies seeking to in-license patents will often employ only the market method or the income method as developing technology in-house is not an option. Licensees should discount the estimated value of the technology by any risk factors specific to the licensing deal (e.g., the proprietary position of the licensor, the market share of the licensee, the length of time before revenue can be generated, the competitiveness of the product or service).

**Proprietary position.** A weak proprietary interest may exist where a patent is questionable in nature; one that covers only a very narrow technology, is very similar to other patented technology or was granted despite potentially not meeting the requirements for patentability. Such a patent does not offer significant market strength because it is either incapable of keeping products or services using similar technology off the market or potentially could be invalidated. Thus, a weaker proprietary interest is a risk factor for the future market success of products or services developed using the licensor's technology. As such, a weaker proprietary position is a factor that licensees can use to negotiate for smaller fees and royalties because large payment obligations would decrease the competitiveness of licensees in a market where the licensed patent does not afford them significant exclusivity, thus harming future market success.

Another significant factor in a licensee's potential proprietary position is the existence, or lack of existence, of third party patents that cover all or part of the technology of interest. In this situation, the license royalty may be significantly discounted in consideration for the need to negotiate additional licenses with third parties. Such a situation also strengthens a licensee's position in favor of stronger indemnification and breach of contract provisions.

**Developmental stage of invention.** Patented inventions that are in the early stage of development often require substantial investment and development before a commercially viable product is produced. But high fees and royalties can compromise the future market success of the licensed technology by siphoning licensee funds away from development and marketing, particularly for an emerging biotechnology company licensee. Licensors are also often less invested, so licensees of early-stage technology should use such effects to negotiate for lower licensing fees and royalties.

**Exclusivity and field of use.** License exclusivity refers to whether the licensor has licensed the invention/technology to multiple licensees, whereas the field of use is the circumstances for which the licensor has granted the licensee permission to make, use and sell the patented technology. It is more advantageous for licensors to grant multiple non-exclusive licenses to further the goal of fully developing the patented technology. The ability of licensors to do so will depend on the strength of their proprietary position. However, such non-exclusive licenses can be limited by the field of use to specific applications, geographical areas, and patent right (manufacture, use, sale). A fairly typical field of use limitation in biotechnology/pharmaceutical licensing is limiting the field of use to a particular disease or group of related diseases. Often the licensee will request and negotiate an option or options for additional fields of use.

Typically, the licensor should aim to grant the narrowest field of use required by the licensee so that the licensor can retain the opportunity to exploit other potential licenses (e.g., where new uses for the technology are discovered or where a single licensee may not have the resources to fully develop the technology). Conversely, the licensee should aim to obtain the broadest field of use because this will provide the opportunity to develop the technology more fully and avoid competition in the market, particularly when the technology is in the early stages of development and the licensee bears the risk of first trying to develop and commercialize a new product or service.

Potential compromise positions include the following: 1) the licensor can grant a broad field of use with the right to retract fields if the licensor presents a use to the licensee and the licensee elects not to pursue it; and 2) the licensor can grant a narrow field of use, with the licensee having the right of first refusal for other uses that the licensor would like to propose to third parties. Alternatively, for generous consideration, a licensee could convince the licensor to restrict any future licensees from particular uses that fall within the licensee's specialty

 

or area of expertise. Even so, where the licensee provided research funds to the licensor to develop the technology, the licensee will typically negotiate for a worldwide, exclusive license for all patents arising out of the research. Such a broad license would give it more control and benefit from the process through sublicensing, even if the licensee lacks the resources to concurrently develop all possible uses or markets for the technology.

Granting a geographically large territory initially is unfavorable to the licensor because it would be incapable of controlling the speed with which the licensee enters the market and may forfeit potential licensing opportunities in those markets. Typically, the licensee will only have sales and marketing capabilities in its domiciled country and may not have the desire or capability to expand adequately into additional markets. Additionally, the licensee will typically only be will to pay an upfront payment for their domiciled country.

**Payment terms.** There are several forms of payment that licensing parties can negotiate to compensate the licensor for the patented technology. For example, when a University is the licensor, a typical license will include a signing fee, reimbursement and ongoing payment of patent prosecution costs, milestone payments, minimum annual royalties and a percentage royalty on sales. A University may also request that the licensee participate in Sponsored Research at the University. One or more of these provisions may be waived if the licensee is a start-up or emerging biotechnology company. In a situation where an emerging biotechnology company is licensing technology to a larger pharmaceutical or biotechnology company, the license agreement may include all of the above but, in addition, require that the licensee fund employee positions (FTE's) at the licensor to work on further development of the licensed technology.

The license or signing fee-essentially the "cost of admission" for the licensee-helps the licensor recoup some of its investment to date. As such, it is always beneficial for the licensor "to seek substantial upfront payments rather than higher royalties, especially for untried products and/or markets." Also, because this fee "must be recouped before the licensee can begin to realize profit, these payments are strong evidence of licensee commitment. However, a high initial fee does not necessarily mean that the royalty rate must be lower. Licensees, on the other hand, benefit more from low upfront payments, leaving the licensor to be compensated by royalties. Having low upfront payments leaves the licensee with more funds for marketing and sales of the product and decreases the monetary risk of the licensee where the product is untried in the market. The size of the fee largely depends on the developmental stage of the invention or the exclusivity of the license as discussed above.

The purpose of annual or other periodic fees, which typically terminate when royalty payments begin, is to incentivize the licensee to aggressively develop and market the technology. Because licensors face the risk that licensees may be willing to pay such fees to "shelve" the technology, the fees should be sufficient to discourage a licensee from "sitting on the technology" or adequately reward the licensor even if the technology is not exploited. Towards this end, increasing annual fees can be effective. Alternatively, lump sum payments may be more practical than royalty payments where the technology is a part of a complicated piece of equipment or system.

Milestone payments are triggered by typical product or service developmental benchmarks, and serve to compensate the licensor commensurate with the increased value of the licensed technology. Most, if not all, license agreements in the biotechnology/pharmaceutical arts will require a licensee to use "best efforts" to meet such benchmarks (or milestones) in specified time periods, to take the patented technology to market. Typical milestones include designation of a "lead compound", filing of an INDA (Investigational new drug application) or NDA (New drug application), completion of a phase of clinical trials, and first commercial sale. If a licensee is unable to meet the milestones, the license may provide for the reversion of all of the license rights back to the licensor, may provide for loss of exclusivity in one or more fields of use, or combinations thereof. In later stages of development, milestone payments are commonly in the tens of millions of dollars.

Percentage royalty payments are a percentage of the net sales of the product or service. A common method for calculating royalties is the 25 % rule. This rule starts with the premise that, under model cir-

cumstances, the licensor is owed 25 % of the licensee's net invoiced sales. This percentage is the starting point that should be adjusted by comparing the circumstances at hand to the ideal model. The percentage can be negotiated below 25 % based on the specific risks the licensee is bearing, including the fact that this rule would regularly generate royalties for the licensor regardless of the actual future profit performance of the licensee or substantial market fluctuations. Typical or standard royalties in the biotech/pharmaceutical area cover a fairly broad range. For example, a small-molecule composition-of-matter patent can bring a royalty of 10–20%, a large-molecule composition-of-matter patent 8–18% and method claims can bring 5–15%. In the pharmaceutical industry, the current range for royalty rates is from ~ 2% for a just discovered or engineered compound or material to ~ 20% for a fully developed product approved for sale.

Licensors should require a minimum annual royalty payment, particularly after the early years of the license agreement, to ensure that the licensee is aggressively marketing and selling the licensed technology or else to trigger possible termination of the agreement due to insufficient monetary returns, thus allowing the licensor to find a more appropriate licensee. Licensees, however, typically wish to avoid high minimum royalty payments, especially during the early years of the agreement, because it usually takes longer than expected to bring a product to market and because failing to meet the minimum could forfeit the license. But, if a licensee desires exclusivity, licensors often require a minimum royalty payment.

Acceptable minimum royalty payments should reflect [...] results which are at the low end of the licensor's acceptable range for returns. At a minimum, to avoid unnecessary contract termination, licensees should negotiate for a provision enabling them to pay a minimum royalty from either surplus royalty payments or general corporate funds. The licensor may also require the discretionary option of reducing of the rights of license if the minimum is not met. Where a licensee has conducted royalty stacking (i.e., licensed multiple different technologies from different licensors to combine into the final product or service), it should negotiate with its licensors to deduct some or all of the royalties paid to third parties from the amounts payable to each licensor, though this is undesirable from a licensor's perspective.

Where a licensor is financially weaker than the licensee, it may desire to negotiate for prepaid royalties, the excess of which can be applied against future royalty obligations. This arrangement helps the licensor to recoup its monetary investment into developing the licensed technology, while not impairing the marketing ability of the licensee.

Also, where the licensor has confidence in the success of the licensee, it can try to negotiate for a higher royalty rate by "offering to share in the licensee's fortunes, good or bad' and risking no royalties if the technology fails to achieve its predictions. This is often useful for licenses for processes to improve efficiency or lower costs, where even marginal increases in efficiency can produce increased profits.

Another expense that can be factored into a license is fees for the patent prosecution program. Subsequent filing of patent applications and correspondence with the U.S. Patent and Trademark Office (Washington, D.C.), for example, in addition to international patent application filings for expansion into foreign markets, can be costly. Thus, licensors can negotiate to have licensees take on the costs of maintaining the patent prosecution program, while retaining the associated rights.

Finally, licensors may seek supplemental remuneration or other types of income. Royalty payments may be reduced or obviated under a variety of circumstances where the licensee can compensate the licensor for the use of the technology in other ways. The licensor may be able to secure the sufficient sale and price of key ingredients, components or special items for the manufacture or use of the licensed technology to the licensee. Alternatively, the licensee may be able to barter or make payments in kind by selling the products or services made under the license back to the licensor at attractive prices. Another potential arrangement is for the licensee to form a new corporate entity for the purpose of executing the license agreement in which the licensor receives a percentage of the voting stock and a veto right for decisions that are considered important to the continued viability of the venture. This arrangement can compensate

 

the licensor by providing equity in the new corporation in exchange for the licensing rights, and places the licensor in a position to influence the conduct of a future market competitor. In addition, the licensor can increase earning potential by requiring a percentage of the income from any sublicenses granted by the licensee.

The profitability of a license can also be increased if the licensor can negotiate to provide special additional services for the licensee (e.g., access to premises, consulting, troubleshooting, sales and service support). Licensees can pay for service fees via annual retainers or per diem charges, though often a certain amount of services could be provided free of charge. Because the licensor has a vested interest in seeing the licensed technology successfully commercialized, if these services are not expressly provided for in the agreement, the licensor can end up giving vast amounts of assistance and support with little or no consideration. Even so, limited or unlimited services and support is critical to any successful license, particularly where the licensee is unfamiliar with the technology or the technology is still in the early phases of development. Thus, to speed entrance of the technology into the market, limiting services and support and requiring compensation for them, will incentivize licensees to avoid delay that could jeopardize the amount of assistance and support they are entitled to under the license agreement or cost them significantly.

**Rights to improvements.** Parties should negotiate provisions to address the ownership of any current or future improvements of the technology. A licensee will want the right to use any variation of the technology claimed in the patent and developed by it or the licensor after the license agreement is entered into so that it does not need to renegotiate a license if the uses become desirable to it. Where improvements are developed by the licensee after the signing of the agreement, the parties will need to negotiate who will own the rights to the improvements. This will largely depend on circumstances before the contract: the relative bargaining strength of the parties, the developmental stage the technology, the potential market for new technologies.

## Conclusion

Licensing can be, and is often, essential for the maximum development of biological and pharmaceutical inventions. Licensing arrangements can be specifically tailored to meet the legal and regulatory requirements of different jurisdictions, as well as the specific needs and capabilities of the parties, and characteristically includes provisions dealing with improvements to the licensed technology and to the granting of patent rights for that technology. By approaching licensing transactions for biotechnological/pharmaceutical technology in a well-planned, forward-thinking manner, both licensees and licensors, particularly those with different types of expertise, can maximize mutual benefits and establish a framework for a solid working relationship in the future. The best practices outlined here provide perspective on the negotiation process as a whole and should aid parties contemplating licensing arrangements for biotechnological and pharmaceutical inventions in establishing the proper approach for the transaction.