Negotiating an Agreement: Skills, Tactics, and Best Practices

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ABSTRACT

License negotiations involve substantial real or potential value. They therefore should be supported by a team of experts. The essential skills and expertise needed for conducting successful negotiations include: business strategy and development for leading the negotiations, marketing for estimating commercial potential, law for evaluating IP and patents and carrying out a variety of related tasks, science and medicine for evaluating new and potential health products, manufacturing and production know-how to determine equipment and additional training needs, and finance for analyzing input from other experts on the team to combine into a comprehensive report. The strength of such a team is in its interdisciplinary composition; each of the skill areas can complement the other. From the perspective of international licensing, licensors can seek to improve the availability of health products in developing countries, possibly moving from the "traditional" approach to licensing toward one that incorporates public sector needs. The best approach for a public sector organization negotiating an agreement with a private sector entity is usually to offer initial terms that the organization would be willing to agree to if it were on the other side of the table. Negotiating a fair licensing agreement should not be seen as a process of "bargaining." Rather, a licensing agreement is establishing, in written form, the rules of operation for an ongoing relationship where mutual trust and confidence will be necessary for success.

1. INTRODUCTION

An agreement is a means of transferring *value* between two parties. Each party has something of value that the other party needs or desires. For example, one party may have a product that can potentially have a very large market, while the other party has research, manufacturing, or distribution capabilities essential to reaching that market. Therefore, the key to successful negotiation is having a clear understanding of the value each party brings to the relationship. Value has several facets. There is an objective value: represented by, for example, how many units can be sold at a certain price, yielding a certain level of profit. There are also qualitative values illustrated by these examples: (1) One company feels that a particular product, owned by a second company, would enhance or complete a particular product line. For instance, it produces hepatitis B vaccine and would like to have a hepatitis A vaccine; and (2) One company may believe that access to a certain product, owned by a second company, would allow it to develop the expertise to handle other similar products. By learning how to produce recombinant DNA hepatitis B vaccine, the first company enhances its capability to produce other recombinant health products in the future. It is important that both parties to a potential agreement think carefully about the benefits that will or could be obtained through a license agreement. Only with a clear understanding of the transfer of value can both parties intelligently and fairly negotiate an agreement.

This chapter should be of help mainly to the public sector R&D organization that is

Mahoney RT. 2007. Negotiating an Agreement: Skills, Tactics, and Best Practices. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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either in-licensing the technology it needs or out-licensing technology it has developed. The discussion applies to a technology that is quite advanced in development. Nevertheless, the information should also be of use to university technology transfer managers and others who are not necessarily directly connected with ongoing R&D programs.

We discuss the licensing process from three points of view: the skills needed, the tactics used, and the practices employed to protect the interests of the public sector.

2. SKILLS NEEDED

Because a license negotiation involves substantial real or potential value, it should be supported by a team of experts. Private sector managers commonly complain that public sector organizations are poorly prepared to undertake effective negotiations, often demand unrealistic conditions, and cannot present a convincing case about the reasonableness of their demands. Obviously, we can do better.

There may be only one or two persons conducting the negotiations, but they should be able to call upon experts in different areas. The following are essential skills for negotiations:

- business strategy or business development
- marketing
- law
- science and medicine, including regulation
- production
- finance

2.1 *Business strategy*

Often, the business strategist is the lead negotiator. With considerable experience in structuring business relationships, the strategist will use the inputs of all the other experts to assemble the negotiating package. This person needs to have a clear sense of how the particular negotiation relates to the overall goals of the organization. This is important because without this sense, the negotiations may lead to a result that will not be useful to the organization. After all, signing an agreement does not necessarily mean that negotiations were successful. The business strategist's goal is to maximize the benefits to all parties. Of particular concern is developing a strategy to be implemented by public sector organizations that helps to ensure that the resulting product is available, appropriate, adoptable, and affordable by the poor in developing countries. Such a strategy, known as a global access strategy,[1] has been the focus of much analysis recently, and the business strategist and his or her team should have prepared a global access strategy, as appropriate for their product. The negotiations of a license agreement should lead to terms that help achieve the specific goals of the strategy, which are defined in the agreement.

2.2 *Marketing*

Expertise in marketing and market analysis is essential to negotiating a good agreement. Omission is dangerous because it can lead either to an overestimation or underestimation of the market potential, which, in turn, can lead to a suboptimal agreement or a rejection of an agreement that could have been successful. Lack of marketing knowledge may also make it difficult to negotiate the best (fairest) deal. In the context of this *Handbook*, we define markets as both private sector markets and public sector health systems. For products such as a malaria vaccine, the public sector market will often be the most important, but an understanding of the travelers' market in developed countries will also be essential. A marketing specialist should ask the following questions:

- What level of sophistication is required to market the product?
- How does the new product complement or compete with existing products?
- Would the product be directed at old or new customer groups?
- If the product is to be sold in both the public and private sectors, what are the barriers to achieving a profitable market?
- What types of information would be needed to promote the product to both the government and the private sector?
- What are feasible prices and would these prices be sufficient to support the project?
- How fast would the market grow and what would be the minimum sales for sustainability/profitability?

With the answers to these questions in hand, the public sector agency will be well prepared to conduct negotiations.

2.3 *Law*

The need for legal assistance is clear.[2] The lawyer should possess IP expertise, be able to evaluate patents, and have a variety of additional skills or be able to access those skills. A party wishing to license a technology will need to be able to assess the value of the patents. This assessment will include an evaluation of the claims of other similar patents. While patent offices try to avoid granting patents with duplicate claims, it is very common to find many patents with the same or similar claims, especially for health products—a number of patents may be issued that claim different methods to produce the same health product. The lawyer will need to determine the potential for claims of patent infringement. The lawyer might also advise on the need to obtain a license from another patent holder before using the offered patent. This assessment (called a freedom to operate assessment) will help in determining the true value of a patent. Such an assessment would answer the questions: Are there other patents that actually are more important? Who owns them? A lawyer will also be needed to advise on the laws of the various countries in which work would be carried out. For example, it may be necessary to evaluate the legal aspects of various arrangements for paying up-front fees and royalties. Some countries tax royalty payments quite heavily but have low or no tax on legitimate charges for technology transfer. Other legal, country-specific matters include validity of termination conditions and validity/enforcement of milestone conditions.

2.4 *Science, medicine, and regulations*

The negotiating team should have scientists and medical experts who are knowledgeable about the products under discussion. In this age of highly sophisticated science, a lead negotiator would be ill-advised to proceed without obtaining good scientific advice about a new health product technology. Not only is it important to assess the feasibility of the new product from a scientific point of view, but it is also important to know what is going on in the field broadly. One must ask, for example, if there were several methods for production of a health product: Which is best? Which is easiest to control? What are the safety considerations of each? It is also important to understand the regulatory framework, or lack thereof, for the potential new product. What kinds of clinical trials, in how many settings, and for what length of time will be needed? In the absence of a regulatory framework for a truly innovative product, how can such a framework be created and how long will it take?

2.5 *Production*

The production staff also should be involved in the licensing negotiation. They need to contribute their knowledge about required production equipment, the needs for additional training, and facility requirements. Production experts can also provide cost estimates for establishing production and for approximating variable costs at given production volumes. (Variable cost studies help determine the extent to which cost is sensitive to production volumes.) Production staff will also be able to advise on requirements for adequate quality control. For codevelopment agreements, production experts can be indispensable for advising on production feasibility. Product developers working in the lab often are unrealistically optimistic about how easy it will be to produce a product in commercial quantities. Production staff can bring reality to the discussions. A final topic for production experts is to understand the potential costs that might be incurred in different settings (for example, developed versus developing countries). It may be desirable to seek production in a developing country to ensure the lowest costs.

2.6 *Finance*

Before negotiating, carrying out a careful financial assessment of the project is essential. The assessment will help the manager determine what new funds will be required to launch and sustain the project, which will require factoring in such variables as the cost of funds (interest payments), hard currency requirements, break-even points (the length of time it takes to recover the initial

investment given certain assumptions about sales and costs), return on investment, impact of royalties and other technology acquisition fees, and opportunity costs (involving the question, could the money be used more profitably in some other way?). The financial analyst will take inputs from all the other experts and combine them to prepare a report.

It should be clear that each of the skill areas complements the others. For example, in a technology licensing agreement, it will be necessary to assess the relative capabilities of the potential licensee's production and marketing departments. A licensee might be strong in production but weak in marketing, or strong in marketing but weak in production. If the differences are too great, implementing the agreement may be difficult. In these cases, the agreement should have tangible performance obligations for activities in which the firm is weak and flexibility where the firm is strong. The marketing, finance, and production staffs will need to work together to complete these assessments.

Not all groups have direct access to a complete complement of staff resources. In those cases, expertise could be obtained through consultants or related institutions that do have the capabilities.

3. TACTICS FOR NEGOTIATING A LICENSE AGREEMENT

Once two organizations have decided to seek to conclude a licensing agreement between them, the first step is to designate the negotiating teams. Each organization should clearly indicate who the members of the negotiating team are and what their respective responsibilities are. The principle line of communication should be between the two lead negotiators. However, the two groups may need to exchange technical information. For example, it may be necessary for one organization to share scientific information with the other. In that case, the scientific staff of each organization should carry out the exchange. Or it may be necessary to go into technical detail about production issues, in which case the production staff of each organization should be involved. When there is an exchange of technical information, the discussion should be limited to the information itself, and the technical individuals should not enter into any negotiations with respect to the licensing agreement unless such involvement is requested by the lead negotiator.

In general, the public sector organization should offer the first draft of a licensing agreement. This approach is much easier than trying to work from a draft prepared by the private sector organization because the draft needs to cover a number of topics of particular concern to public sector organizations, and these topics probably would not be addressed in a private sector organization's draft. The topics of concern are jurisdiction, liability issues, ownership of IP, protection of the public sector, and others. It is much easier to start with a draft that has all of these issues clearly laid out—and is based on previous experience—than to try to insert those issues into a draft that does not include them.

The public sector organization's lead negotiator may ask for examples of the kind of agreement that the other organization feels comfortable with. The lead negotiator may extract some of the key wording in clauses from the example agreements and insert them in the prototype of the public sector organization agreement. In certain cases, primarily for in-licensing, it may be necessary to use the private sector organization's standard agreement, either because the organization requires that its agreement be used or because it has extensive experience in the kind of licensing agreement at issue, and time and energy would be saved.

One variation in developing a first draft of a license agreement is to prepare a *term sheet*. A term sheet lists the major issues that are expected to arise in the negotiations and indicates the outcome that the proposing party hopes to achieve. For example, if the agreement includes the development of a commercially viable production process, the term sheet would indicate a schedule for achieving various stages of production capability, the number of units to be produced, and the quality standards that the units would have to meet. A term sheet is a straightforward way for the parties to discuss key issues without having to wade

through a long document that contains a lot of routine boilerplate. Table 1 provides an example of a term sheet for a clinical testing agreement.

The best approach for a public sector organization negotiating an agreement with a private sector entity is usually to offer initial terms that the organization would be willing to agree to if it were on the other side of the table. Negotiating a fair licensing agreement should not be seen as a process of "bargaining." This is because a licensing agreement establishes, in written form, the rules of operation for an ongoing relationship where mutual trust and confidence will be necessary for success.

At the beginning of the negotiations, it is important for each group to clearly state what it hopes to achieve from the negotiations, although, of course, there will always be confidential

Table 1: Prototype Term Sheet to Facilitate Negotiations

Term Sheet	
Clinical Research Agreement	
Territory	Kenya
Phase I/II conducted by [DATE]	
Initiation	2007
Completion	2008
Subjects	250
Funding	100% paid by [DATE]
Phase III conducted by [DATE]	
Initiation	2009 or 2010
Completion	2012
Subjects	10,000
Funding	100% paid by [DATE]
Diligence	
Phase I/II initiation by [DATE]	1/1/07
Phase III initiation by [DATE]	1/1/10
Regulatory submission by [DATE]	1/1/12
Clinical trial design by [DATE]	Licensor consent
Manufacturing	Licensor or its agent
Transfer prices to [DATE]	
ncGMP (noncurrent good manufacturing practice) material for phase I/II trial	Paid by licensor
cGMP (current good manufacturing practice) material, per unit	US$10
Cost sharing for manufacturing scale-up	To be determined
Investigational New Drug (IND) preparation by licensor	$0
Quality control monitor for clinical trial	100% paid by [DATE]
Regulatory license holder	[DATE]
Indemnification	[DATE] indemnifies licensor

information that cannot be revealed. The public sector organization may be interested in working with a group that can develop a superb and economical production methodology for a new product that the public sector organization has developed. The counterpart organization may be interested in participating in the development of regulatory guidelines for a particular kind of product. By stating their primary objectives clearly at the beginning of the negotiations, it will be easier for both parties to take into account the needs of the other.

Negotiating a license agreement often takes much longer than either party would like. This can be frustrating for the technical staff of the public sector organization, who would like to resume research and development activities as rapidly as possible but have to put on hold many such activities until the license agreement is signed. There are a number of reasons why license negotiations often take longer than anticipated. The license must be approved at multiple levels in each organization and will undergo review from technical, financial, legal, and other experts with varying points of view. Often the views may differ internally, which requires internal negotiations that take some time to resolve.

4. PRACTICES TO PROTECT THE INTERESTS OF THE PUBLIC SECTOR

Table 2 illustrates how licensors can seek to improve the availability of health products in developing countries. It summarizes the "traditional" approach to licensing and then indicates a more public sector option.

Two examples of a clause pertaining to territory are provided below. The clause is for use in agricultural research and development but can be adapted to health research and development. The clause would be used in a license issued by a university to a private company.

Example 1: Public Intellectual Property Resource for Agriculture (PIPRA)[3]

Definition of Humanitarian Use:

Definitions:

"Humanitarian Purposes" means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a Developing Country.

"Commercial Purposes" means to make, have made, propagate, have propagated, use, have used, import, or export a product, good or service for the purpose of selling or offering to sell such product, good or service."

"Developing Country" means any one of those countries identified as low-income or lower-middle-income economies by the World Bank Group at the time of the effective date of this agreement and all other countries mutually agreed to by Licensor and Licensee.

Reservation of rights

Notwithstanding other provision of rights granted under this agreement, University hereby reserves an irrevocable, nonexclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.

Table 2: Illustrations of Best Practices for Licensing to Meet Public Sector Goals

Topic	Basic concept	Public sector consideration
Areas of use	This clause specifies the limitations on the application of the patent in developing products. The simplest approach is to grant the licensee an exclusive right to all possible applications of the patent, including not only those specified in the patent, but others that may emerge as further research and development proceeds.	The clause could grant an exclusive license only for those products that the licensor actually wishes to pursue. Also, the clause could grant an exclusive license only for those products that were unlikely to have a significant market among the poor in developing countries.
Territory	This clause specifies the geographic areas in which the licensee has the right to exercise the patent. The simplest approach is to grant the licensee an exclusive right to all possible territories. Usually a license is valid only in the countries where a patent has been filed, but the license can give the licensee the right, at the licensee's expense, to file for patent protection in additional countries.	The clause could grant an exclusive right to a major portion of developed countries, for example, North America. The licensor could grant another exclusive limited license to countries in Europe. Finally, the licensor could grant nonexclusive licenses to both licensees for an agreed list of developing countries. Then the two primary licensees would have to compete for sales to developing countries.
Price	In most licensing agreements, there will be no conditions with respect to price. The licensor assumes the licensee will determine the best price to ensure the greatest return on investment.	The licensor can consider several options of setting a condition of the price to the public sector in developing countries. • The price could be specified, for example, US$0.30 per tablet. This is feasible only when the licensor has detailed technical knowledge of the production, marketing, and distribution costs. • The price could be set at cost of production plus a reasonable markup, for example, 15% of cost of production. This is feasible when the licensor has a reasonable expectation of being able to monitor the cost of production. • The price could be set at "no higher than the lowest price offered to any private sector buyer." This may be preferred in cases where it is expected there will be large bulk purchases by private sector buyers who are good at negotiating the very best price.

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Table 2 (continued)

Topic	Basic concept	Public sector consideration
Labeling	In most licensing agreements, there will be no conditions about labeling. The licensor assumes the licensee will prepare labeling in conformity with national drug regulatory agency requirements.	The licensor can help ensure that the product is licensed properly, especially in developing countries where national regulatory agency requirements for labeling may not be rigorous or enforced. For example, if some of the research that led to the patent was supported by the World Health Organization (WHO), the license can specify that the name of WHO cannot be used without prior written approval of WHO. Additionally, the license could state that any claims for the use, safety, and effectiveness of the product should receive prior written approval.
White knight condition	This concept has been developed by the U.S. National Institutes of Health. It calls for the licensee to undertake some specific actions that will benefit the public sector.	The licensor can ask for a number of actions including donation of product for clinical evaluation in public sector research programs, joint efforts to develop markets in developing countries, free supply under specified condition to developing countries, and so on.

Example 2: Donald Danforth Plant Science Center

Reservation of IP Rights for Humanitarian Purposes

COMPANY and Danforth shall diligently and in good faith negotiate the terms of the license, making provision for preserving the availability of the Intellectual Property for meeting the needs of developing countries.

or

Danforth shall retain the right to use Phase I Materials and Phase II Materials for both academic and commercial research purposes, which shall include the right to use such technology for the benefit of countries eligible for International Development Association funds as reported in the most recent World Bank Annual Report.

This clause has been part of the Donald Danforth Plant Science Center's IP policy since 2002.[4]

5. CONCLUSION

The negotiation of licenses is a complex undertaking that involves various tactics and a variety of skills. To meet the needs of the public sector, the negotiations should include special considerations in many clauses of the agreement. Moreover, because IP management involves matters of real or potential considerable value, it should be given the resources and personnel it needs to do the job well. No serious private sector company would enter into IP negotiations without allocating an appropriate level of resources and personnel. Because public sector research organizations are

concerned with saving human life, their imperative to do the same should be no less. ■

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1 Mahoney RT, A Krattiger, JD Clemens and R Curtiss. 2007. The Introduction of New Vaccines into Developing Countries IV: Global Access Strategies. *Vaccine* (in press). See also Krattiger A, et al. 2006. Global Access Strategy for the live recombinant attenuated Salmonella anti-pneumococcal vaccine for newborns. Arizona State University: Tempe. www.biodesign.asu.edu/centers/idv/projects/, and Anonymous. 2006. Strategic Plan. Dengue Vaccines: The Role of the Pediatric Dengue Vaccine Initiative. Strategic Partnerships, Supportive Research & Development, Evaluation, and Access. International Vaccine Institute: Seoul. http://www.pdvi.org/PDFs/PDVI%20Strategic%20Plan.pdf.

2 See, also in this *Handbook,* chapter 6.10 by J Dodds and chapter 6.9 by M Goldman.

3 www.pipra.org/docs/HumResLanguagePIPRA.doc. See, also in this *Handbook*, chapter 2.1 by AB Bennett.

4 Beachy R. 2006. Donald Danforth Plant Science Center. St. Louis, U.S.A. Personal communications. See, also in this *Handbook*, chapter 17.9 by K Schubert.