Life Sciences Patent Licensing

Key Considerations in Deal Negotiations

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Scope Note

This article, Life Sciences Patent Licensing, addresses contractual and intellectual property considerations that frequently arise in the drafting and negotiation of intellectual property license agreements in the life sciences industry, and in particular, license agreements for patented compounds or biological materials. For ease of reference, these will be simply referred to as the "Compound," and it is assumed that the licensor has a proprietary interest (either as the patent owner or as the exclusive licensee from a third party) in the Compound that is the subject of the license agreement. The topics to be covered are field of use restrictions (Article I); Compounds with possible multiple applications or the "multi-purpose compound" (Article II); special issues related to non-exclusive licenses (Article III); payment terms (Article IV); and rights to the drug master file upon early termination of the license agreement (Article V). The Sample Collaboration and License Agreement included in the Appendix illustrates many of the topics discussed below. The Appendix also includes sample provisions for dealing with the multi-purpose compound.

Field of Use

As the name suggests, a field of use provision in a license agreement limits the licensee's rights in the licensed technology to specified applications or uses. Typically, the field of use restriction is first presented in the definitional section of the license agreement and is usually referred to as the "Licensed Field" or the "Field". The Field will then appear in the license grant provision of the license agreement, where it serves as a limitation on the rights granted to the licensee. For example, a license grant provision with a field of use restriction may state that, "Licensor hereby grants to Licensee an exclusive license under the Licensed Patents to make, have made, use, offer for sale, sell, have sold, and import Licensed Products in the Field."

Field of use restrictions deserve special consideration in the licensing of intellectual property. Consider for example, a Compound that may have potential therapeutic and/or diagnostic uses for several disease indications in both humans and animals. In the absence of a field of use restriction in the license agreement, the licensee would have rights to exploit the Compound across all fields of use. Conversely, if the license agreement includes a field of use restriction, but it is not carefully considered and drafted, the licensee may be deprived of the necessary rights that it needs to fully exploit the licensed technology in furtherance of the licensee's business objectives. Accordingly, a key objective in drafting field of use restrictions should be to clearly and unambiguously define the scope of the licensee's authorized field of use, so that each party (and a court, if it ever came to that) can objectively determine what uses or applications are

included within the scope of the license, and what uses or applications are excluded.

From the licensor's perspective, it would be preferable to grant the licensee a narrow field of use that provides the licensee with the rights that it needs to execute on its business objectives, while preserving the opportunity for the licensor to exploit other potentially useful applications of the Compound. For example, consider that there may be early results suggesting that the Compound may have efficacy for two very disparate diseases, such as brain tumors and stomach ulcers (not likely, but a stark example to emphasize this point). A prospective licensee may have interest in the Compound, but its business focus is isolated to oncology and, therefore, the licensee's primary interest is in securing rights to the potential uses of the Compound to treat brain tumors. If the owner of the Compound exclusively licenses its rights to the prospective licensee without a field of use restriction, the owner has likely deprived itself of the opportunity to further develop (either itself or through another licensee) the Compound for the treatment of stomach ulcers (or any other use that may be subsequently identified through further research). As a result, a potentially valuable use of the Compound may never be exploited. Therefore, it may be in the interest of the licensor to grant the prospective licensee a field-limited license that permits the licensee to effectively exploit the Compound in its desired field of use, without depriving the licensor of the opportunity to exploit the other potential uses. In other words, from the licensor's perspective, it is a matter of maximizing the potential value of its inventions.

On the other hand, from a prospective licensee's perspective, it would be preferable to negotiate a field of use that is as broad as possible (for example, to all therapeutic uses of the Compound in humans or to oncology in general) or, more preferably, no field of use restriction. The outcome of these negotiations may depend on the Compound's stage of development. For example, if the Compound is in the very early stages of development and the licensor has not yet granted other third-party licenses, the licensor may be willing to consider a broader field of use license, particularly if the prospective licensee intends to fund substantially all of the Compound's subsequent development and is willing to assume the early development risk. On the other hand, if the Compound is more fully developed and there are already other third-party licenses in place, the prospective licensee may have to accept a more limited field of use.

Practice Tips

How do you bridge these competing interests? There are a number of options, of which two are often used. The licensor can agree to a broader field of use (or none at all), but have the right to take back unexploited applications in the field of use if the licensor presents the unexploited application to the licensee (with some supporting evidence of viability), but the licensee subsequently elects not to pursue that application. Another solution may be for the licensee to agree to accept a narrow field of use but have a right of first refusal or a right of first negotiation on other applications that the licensor proposes to out-license to third parties.

A licensee's practice of the licensed technology outside of the defined field of use would constitute an unlicensed use of the licensed technology, potentially subjecting the licensee to claims of intellectual property infringement or misappropriation. The licensor's inclusion of a provision in the license agreement that affirmatively precludes a licensee from operating outside the licensed field of use may be helpful in establishing a contractual right for the licensor to terminate the license agreement if the licensee operates outside the authorized field of use and to sue the licensee for breach of contract, rather than relying on the licensor's rights to sue its licensee for intellectual property infringement or misappropriation.

See Sections 1.21, 1.24 and 9 of the Sample Collaboration and License Agreement.

The Multi-Purpose Compound

Suppose that the prospective licensee has been sponsoring research at a company or academic institution, and the sponsored research leads to the discovery of a Compound that shows some early clinical promise. The early indications are related to stomach ulcers, but it is too early in the

research to know whether there are any other possible indications. Meanwhile, the clock is ticking under the prospective licensee's sponsored research agreement to exercise its option and negotiate the terms of the license to the Compound and the corresponding intellectual property. The prospective licensee elects to exercise its option under the sponsored research agreement. What does it get? The right to negotiate the terms of a license to the Compound for all potential uses, or just for a particular indication, stomach ulcers? The multi-purpose compound presents many of the same issues and considerations that are addressed above in the discussion of field of use restrictions.

From the perspective of the prospective licensor, it would prefer to grant the licensee a narrow license in order to maximize the potential of the multi-purpose compound through multiple license grants and development programs. The prospective licensor could achieve this by using a carefully crafted field of use restrictions in each license agreement. Through this licensing program, such a prospective licensor could achieve concurrent development of the Compound in different fields of use by a number of licensees, something that a single licensee may not have the capability or resources to undertake itself.

From the prospective licensee's perspective, for all the reasons discussed above, a world-wide exclusive license to the Compound and all of the associated intellectual property may be preferable. Having paid for the discovery of the multi-purpose compound, the prospective licensee's position may be that it is entitled to all of the potential value arising from its discoveries. Even if the prospective licensee does not have the resources necessary to engage in the concurrent development of the Compound across multiple fields of use, it would like the right to control and benefit from that process through a sublicensing program.

Practice Tips

In the sponsored research context, you may be able to avoid these issues by addressing them in the funding agreement. A prospective licensee providing all or substantially all of the funding to the prospective licensor for a specific research program may have more success negotiating for broader rights to all discoveries arising from the funded program. The funding agreement should be unequivocal if that is the case. If the prospective licensee has not provided funding and is negotiating with the prospective licensor after it has made a discovery, the prospective licensor may be reluctant to grant the prospective licensee exclusive rights across all fields of use, but would instead likely seek to limit the authorized uses.

See the Sample Provisions to Address the Multi-Purpose Compound included in the Appendix.

Non-Exclusive License Agreements

If the owner of an invention has granted a licensee a non-exclusive license to that invention, the owner has reserved for itself the right to grant one or more other non-exclusive licenses to third parties. Unless their licenses are limited by field of use or by territory, the licensees under non-exclusive licenses may exploit the subject invention worldwide for all uses. In other words, each licensee may find itself in competition with other licensees seeking to exploit the same invention. Obviously, licensees would likely insist on exclusivity before investing significant resources in a development program in order to limit potential competition and maximize its potential return, while licensors might prefer non-exclusive licensing in order to maximize the value of an invention.

In the life sciences industry, non-exclusive licenses are frequently limited to intellectual property that may be generally supportive of the development program. For example, suppose that a prospective licensor has invented a method to formulate certain compounds to achieve a sustained, measured release of the compound over a period of time. The prospective licensor may seek to undertake a program of non-exclusive licensing of the technology in order to maximize the value of its invention. In this case, a prospective licensee may be willing to consider taking a non-exclusive license to such drug delivery system if the rights to the corresponding

compound are exclusively controlled by the licensee. While a prospective licensee might wish to monopolize (through an exclusive license) such a drug delivery system because of the competitive advantage it gives to its product, the licensor may not agree. Instead, a shrewd licensor may insist on a non-exclusive license, although the aggressive licensee offering the right incentives may be able to negotiate for an exclusive license to the drug delivery technology in a limited field of use. For example, for more generous economic terms, a licensee might successfully persuade a prospective licensor to restrict all other licensees from using the invention for the prospective licensee's compound or for the treatment of a specific application, subject to any other licenses that may have previously been granted by the prospective licensor.

Due to the prohibitive cost of developing a pharmaceutical product, non-exclusive licenses of Compounds with therapeutic potential are rare because a licensee would likely not undertake the development without the benefit of the exclusivity afforded by an exclusive license. But it should be noted that an exclusive license of a Compound that is limited to a narrow field of use, such as a specified disease indication, presents some of the same concerns to the licensee as a non-exclusive license because the licensor can grant "exclusive" licenses for other fields of use. This can be problematic because of the potential for off-label use of pharmaceutical products. To use a stark and somewhat unlikely example, suppose that a licensor has granted an exclusive license of its proprietary Compound to a licensee for "therapeutic use in humans but no other uses." Suppose that the licensor then grants another exclusive license of its Compound to a third-party licensee for "therapeutic use in animals but no other uses." Suppose further that both licensees proceed to develop the same or substantially the same formulation of the Compound and each introduces that product into the marketplace. Two things are certain: the licensee of the Compound for uses in animals will likely have spent far less to develop its product compared to the licensee of the human counterpart product; and the price for the Compound for use in animals will likely be much less than the price of its human counterpart product. What's to stop potential consumers of the human product from buying the animal product?

From the licensor's perspective, non-exclusive licensing may seem to be the best way to maximize the potential value of an invention. On the other hand, a licensor must evaluate certain factors before committing to its licensing strategy. Will prospective licensees take a non-exclusive license? While multiple non-exclusive licenses are possible, would a single exclusive licensee exploit the invention more fully than multiple licensees? Is there a risk that one non-exclusive licensee's development program for the Compound could interfere with another's non-exclusive licensee's development program? Could value be maximized by multiple "exclusive" licenses in narrowly defined fields of use? These are all relevant considerations for a licensor before committing to what may be an irreversible licensing strategy when it grants its first license.

From the licensee's perspective, it generally would prefer an exclusive license, even if limited to a narrow field of use. The considerations and stakes are very different when the subject matter of the license is a Compound as opposed to, for example, a drug delivery system or other peripherally relevant invention.

Practice Tips

A licensor should decide on its licensing strategy before it grants its first license because once an exclusive license has been granted (unless limited by field of use or territory), the licensor may be precluded from subsequently granting non-exclusive licenses, and *vice versa*. A prospective licensee must undertake due diligence with respect to the scope of any licenses previously granted to the same invention. While you probably will not learn the economic terms of these previous licenses, the prospective licensee needs to have a clear understanding of what rights were previously granted, to whom, and for what uses in what territories. Importantly, a prospective licensee needs to understand whether there are sufficient rights available for licensing its intended use of the invention, and what risks may be presented by the licensor's having authorized other licensees to practice the invention. If a prospective licensee is prepared to take a non-exclusive license (or an exclusive license with a limited field of use), it should

consider negotiating for an agreement by the licensor that restricts all other licensees from developing the same or substantially similar product that the prospective licensee is developing. Note that this may not be possible if the prospective licensee is not the first licensee. Licensees should seek to include provisions in the license agreement whereby the licensor represents that the grant of rights does not conflict with any outstanding licenses.

See Sections 8.1(d) and 9 of the Sample Collaboration and License Agreement included in the Appendix.

Payment Terms

The economic terms of a license agreement are a key business term to be mutually agreed upon, but merit consideration in light of current licensing practices in the industry for similar inventions. Some or all of the following are common in industry license agreements: an upfront license fee; annual or other recurring fees; milestone payments; earned royalties, which may include minimum annual amounts; and the reimbursement of expenses incurred by the licensor in furtherance of the prosecution, maintenance, and/or enforcement of the licensed intellectual property. All of these are subject to negotiation, and it can't be said that any amount or rate is right or wrong as much depends, as it always does with business terms, on the relative bargaining power of the parties and their assessment of the potential value of the invention.

The size of an upfront license fee, if any, is often dependent on the stage of development of the invention. From the licensor's perspective, an upfront license fee may present an opportunity to recoup some of its investment to date in the work that has led to the invention. How much it might ask a licensee to pay will be influenced in part by whether it intends to pursue a non-exclusive licensing program or to grant an exclusive license. From the licensee's perspective, this fee is the cost of admission. If the licensee highly values the invention, it is getting an exclusive license, and the licensor has invested heavily in development to date, the licensee may be prepared to pay a hefty upfront fee. On the other hand, if the licensee has been funding the research work of the licensor and the invention remains subject to a long and expensive development program to be funded by the licensee, the licensee may only be willing to pay a modest license fee, if any.

Annual or other recurring license fees are often used as a means to incentivize the licensee to exploit the invention. The theory being that the licensee may not be able to justify the payment of high annual fees indefinitely if it is not going to exploit the invention. On the other hand, a licensee might be willing to do just that in order to prevent third parties from gaining access to an exclusively licensed invention. In other words, the exclusive licensee may be willing to pay an annual license fee to "shelve" the invention. A licensor must be aware of this risk and negotiate annual fees (and more preferably diligence obligations) that are robust enough to discourage the licensee from sitting on the invention or that reward the licensor adequately even if the invention is not exploited.

Milestone payments are a common feature of industry license agreements. These payments are usually triggered upon the achievement of designated events which validate the value of the invention. Some common milestone events include:

- Identification of a lead candidate for development
- Filing of IND or equivalent
- Completion of a Phase 1 clinical trial
- Completion of a Phase 2 clinical trial
- Completion of a Phase 3 clinical trial
- Filing of NDA or equivalent

- Approval of NDA or equivalent

If the three phases of the clinical trial process are used as triggers for milestone payments, the license agreement should be clear whether these are achieved by "completion" or "satisfactory completion" of the milestone. The licensee would prefer the latter, as it would indicate that the development is progressing satisfactorily. The licensor, on the other hand, would prefer the former because the licensor will be paid the milestone payment even if the licensee is not satisfied with the results of the clinical trial. In order to avoid the possibility of disagreement of what constitutes "satisfactory completion," the license agreement may provide that commencement of the next phase of the clinical trials is deemed to evidence satisfactory completion of the immediately preceding phase (e.g., commencement of Phase II clinical trials means that Phase I clinical trials have been successfully completed).

Practice Tips

With respect to royalty payments, there are a few practice tips parties should consider when negotiating license agreements. In patent license agreements, the parties should consider clearly distinguishing between pre-expiration and post-expiration royalties, being sure to properly account for the basis for any royalties exacted after expiration of the patents, for example, by tying post-expiration royalties to the licensee's use of additional non-patent rights.

See Section 10 of the Sample Collaboration and License Agreement included in the Appendix for a complete panoply of license payment terms.

Drug Master File

The drug master file is the collection of information and data that results from the development process for a potential pharmaceutical product, such as toxicology studies and clinical trial results. The drug development process is highly regulated and structured in the sense that certain types of tests and procedures must be conducted for all potential products, even if the details of those tests and procedures may differ from potential product to potential product. The drug master file has an inherent value, and an important issue to be considered in industry licensing is the disposition of the drug master file in the event of early termination of the license agreement.

A drug development project can be discontinued even if it has been successful to date. Suppose that the initial licensee of a Compound has carried the program through the filing of an IND and has spent a total of $50 million to date. Suppose further that, while the results have been promising to date, the licensee elects to abandon the program, for example, because it has other more promising projects on its plate and insufficient resources to pursue them all. If the licensee elects to terminate the license agreement, the licensor may consider licensing the Compound to a third party or pursue the project itself.

This is often addressed in the termination provisions of the license agreement, such as in Section 16.5 of the Sample Collaboration and License Agreement. This "no fault" termination provision presents an example of one possible solution to this issue. Under this provision, if after a "no fault" termination of the license agreement by the licensee, the licensor commercializes a product incorporating the Compound, the original licensee may be entitled to compensation, the amount of which depends on the stage of development at which the license agreement was terminated. The compensation is (i) an earned royalty on sales if the licensor itself commercializes a product incorporating the Compound, or (ii) if the licensor licenses the Compound to a third party, a percentage of what the third party licensee pays the licensor in earned royalties, fees, milestone, etc. and reimbursement of a portion of the original licensee's out-of-pocket expenses for its work. For example, if the "no fault" termination takes place during the pre-clinical stage but before the filing of an IND, the original licensee is entitled to an earned royalty of 1.5% on sales by the licensor, and if the licensor licenses to a third party, the original licensee is entitled to 20% of all amounts paid to the licensor by the third party under the license,

and reimbursement of 50% of the original licensee's out-of-pockets expenses incurred for the pre-clinical work that it undertook. If the "no fault" termination takes place after regulatory approval of a product, the corresponding amounts are increased to a 9% earned royalty, 50% of any payments under a third party license, and reimbursement of 100% of out-of-pocket expenses. Thus, the economic terms of the "no fault" termination provision recognize the increasing value of the drug master file as the development process continues.

Practice Tips

Whether you are the prospective licensor or licensee in the negotiation of an industry license agreement, be sure that you consider this issue in the course of negotiating the license agreement. From the licensor's perspective, it would prefer to gain access to and permitted use of the drug master file (and other potentially valuable program data and developments created by the licensee), ideally at no cost, under any early termination scenario. From the licensee's perspective, it may be appropriate to seek some recovery of its investment in the event the drug master file (and other potentially valuable program data and developments created by the licensee) are used to benefit the licensor or a third party.

If you have any questions regarding life sciences patent licensing, or would like to discuss industry intellectual property licensing issues, please contact Stanley F. Chalvire .

Appendix

For copies of the Appendices to this article please contact Jaclyn Braga.

1. Sample Collaboration and License Agreement
2. Sample Provisions to Address the Multi-Purpose Compound