



# Biotech/Patent Licensing

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## SCOPE NOTE

This article addresses contractual and intellectual property considerations that frequently arise in the drafting and negotiation of license agreements in the biotech industry, and in particular license agreements for engineered compounds or biological materials. For ease of reference and in order to avoid becoming bogged down in matters of science (which are beyond the scope of this article and program, and quite frankly me), 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 (Article V). The Sample Collaboration and License Agreement included in the Appendix illustrates many of the matters discussed below. The Appendix also includes sample provisions for dealing with the multi-purpose compound. A disclaimer: My background in this practice area is representing the pharmaceutical company. As a result, this article is biased towards that perspective.

### I. Field of Use

A. 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. Typically, the field of use restriction first pops up in the definitional section of the license agreement, and is usually called the “Field”. It will then appear in the grant of rights or actual license provision, where it serves as a limitation on those rights. For example, a grant clause with a field of use restriction may state that “Licensor hereby grants to Licensee a non-exclusive license of and under the Licensed Patents in the Territory to make, have made, use, sell and import Products for use in the Field”.

B. Field of use restrictions deserve special consideration in biotechnology. Consider a Compound that might have potential preventive, diagnostic or therapeutic uses for several disease indications in both humans and animals. In the absence of field of use restrictions, the licensee would have rights to exploit the Compound in all of those fields, and if the license were exclusive, no one else would. If the license does have field of use restrictions, but they are not carefully considered and drafted, the licensee might not have rights to do what it wants to do. The goal in drafting field of use restrictions is clear and unambiguous language so each party (and a court, if it ever came to that) knows what is included and what isn’t.

C. From the licensor’s perspective, it wants the most narrow field of use that gives the licensee what it wants/needs, but also gives the licensor the opportunity to exploit the other potential uses of the Compound. For example, suppose that there are early indications in the lab that the Compound might have some efficacy for two very disparate diseases, such as brain tumors and stomach ulcers (not likely, but a stark example to make this point). Pharma Company is interested in the Compound, but its focus is cancer and, therefore, its interest is in the potential use to treat brain tumors. It is not likely to

invest in the development of the Compound for stomach ulcers. If the owner of the Compound licenses it to Pharma Company without a field of use restriction to brain tumors, the owner has deprived itself of the opportunity to develop (either itself or through another licensee) the Compound for stomach ulcers (or any other use that might be identified through further research). As a result, the best use of the Compound may never be exploited. Therefore, it is in the interest of the licensor to give the licensee a field of use that permits the licensee to effectively exploit the Compound in its desired field of use, but not to deprive the licensor of the opportunity to exploit the other potential uses. The licensor doesn't want to put all of its eggs in one basket with a licensee which may not have the resources to pursue multiple potential uses. In other words, from the licensor's perspective, it is a matter of maximizing the potential value of its invention.

D. From the licensee's perspective, on the other hand, it wants as broad as possible a field of use (for example, therapeutic use in humans or cancer in general) or, ideally, no field of use restriction. Much will depend, of course, on the stage of development of the Compound. If it is very early stage, there have been no other licenses, and Pharma Company will fund substantially all of the subsequent development, Pharma Company may want and be entitled to a broad field of use because it is first in line and taking the early risk. It does not want to fund further development (to which the licensor often has access and rights) and then miss out on the potential for a blockbuster use that has not yet been identified, but is not included in the licensee's field of use. On the other hand, if the Compound is more fully developed and there are already other licenses in place, Pharma Compound will have to accept a narrower field of use (what hasn't been taken yet by other licensees).

E. ***Practice Tips.***

How do you bridge these conflicting interests? There are a number of possibilities, 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 fields of use (for example, stomach ulcers in the scenario presented above) if the licensor presents the use to the licensee (with some supporting evidence of viability), but the licensee elects not to pursue that use. Another solution is for the licensee to agree to a narrow field of use, but have a right of first refusal on other uses that the licensor proposes to license to third parties.

Be sure that the field of use is as clear and as unambiguous as possible. It will be necessary to get your client's scientists involved if a field of use is proposed that is technically described.

If the parties have agreed to a limited field of use, be clear that all others are not included. For example, instead of defining the field of use as "therapeutic use in humans, but not diagnostic use", define it as "therapeutic use in humans but no other use". A belt and suspenders approach would be to add that the licensor "retains all rights in all fields other than therapeutic use in humans".

The terms of the improvements and grantback provisions must be considered in relation to the field of use restrictions. For example, if the license includes a narrow field of use, but also includes a grantback to the licensor of any improvements made by the licensee, the licensor could have an enormous windfall. Using the same example, suppose the potential use for stomach ulcers is unidentified at the time of the license, and while the licensee is doing its development work related to brain tumors, it stumbles on this potential use. This would be an improvement that is granted back to the licensor. Suppose further that this proves to be the blockbuster use of the Compound. Unless the licensee has some rights in the improvement (beyond the right to use it for the use for which it is licensed), such as a right of first refusal to license the improvement or a participation in the economic benefits from the commercialization of the improvement (such as a royalty on sales by the licensor or a third party licensee), the licensee will have lost out entirely on something it discovered.

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

## II. The Multi-Purpose Compound

A. Suppose that your client Pharma Company has been sponsoring research at Baby Biotech that leads to the discovery of an engineered peptide that shows some promise. The early indications are possible activity related to stomach ulcers, but it is too early in the research to know if there are any other possible indications or targets. Meanwhile, the clock is ticking under your client's sponsored research agreement to exercise its option for a license of the patents (at this stage, patent applications) on the engineered peptide. Your client exercises its option. What does it get? A license of the patents for all potential uses (at this stage in the patent prosecution strategy, the patent application would be as broad as possible) or just for 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.

B. From the perspective of Baby Biotech, the licensor, it would prefer a narrow license in order to maximize the potential of the multi-purpose compound through multiple license grants. It would achieve this by carefully crafted field of use restrictions in each license. Through this program, it could achieve concurrent development of the peptide by a number of licensees with available resources, something that a single licensee, especially in the pharmaceutical industry, is unlikely to be able to undertake.

C. From your client's perspective, it would like, for all the reasons discussed above, a world-wide exclusive license of and under all of the patents related to the engineered peptide. Having paid for the discovery of the multi-purpose compound, its position is that it is entitled to all of the potential value of the discovery. Even if it does not have the resources necessary to engage in concurrent development for possible different indications, it would like the right to control and benefit from that process through a sublicensing program.

D. *Practice Tips.*

In the sponsored research context, you may be able to avoid these issues by addressing them in the funding agreement. If you are representing Pharma Company and it is providing all or substantially all of the funding to Baby Biotech for a specific research program, it likely will be able to negotiate for all rights in all discoveries from the program. The funding agreement should be unequivocal if that is the case. If your client has not provided funding and is negotiating with Baby Biotech after it has made a discovery, your client will likely not get all fields, but will probably be limited to the uses that are its specialty (most pharma companies focus on one or a few disease indications). If your client Pharma Company is sponsoring research at a university, its rights are also likely to be limited. The special considerations involved in university licensing are addressed in another part of this program. See the Sample Provisions to Address the Multi-Purpose Compound included in the Appendix.

### **III. Non-Exclusive License Agreements**

A. If the owner of an invention has granted a non-exclusive license of the invention, it has reserved the right to grant one or more other non-exclusive licenses. Unless their licenses are limited by field of use or territory, the licensees under non-exclusive licenses may exploit the subject invention for all uses and everywhere. In other words, they may engage in full-scale head-to-head competition trying to exploit the same invention. Obviously, licensees would prefer exclusivity in order to avoid potential competition, while licensors might prefer non-exclusive licensing in order to maximize the potential of an invention.

B. In the biotech and pharmaceutical arenas, non-exclusive licensing is generally confined to what I call peripheral inventions, such as drug delivery systems or discovery methods. Suppose your client has invented a method to formulate certain kinds of small molecules to achieve a sustained, measured release of the small molecule in the patient over a period of time. Your client would undertake a program of non-exclusive licensing in order to maximize the value of the invention. In this case, a pharma company licensee is willing to take a non-exclusive license because it will have a legal monopoly as a result of coupling its patented small molecule with the drug delivery system. While a pharma company licensee might wish to monopolize (through an exclusive license) such a drug delivery system because of the competitive advantage it gives to its product, it is not likely that the licensor will agree. The shrewd licensor will stick to non-exclusive licensing, although the aggressive licensee offering the right incentives might be able to negotiate for an "exclusive" in a limited field of use. For example, for more generous economic terms, a pharma company might persuade your client to restrict all other licensees from using the invention for products that treat stomach ulcers, which is the pharma company's specialty. Obviously, what any licensee can get is much dependent on what has already been granted to existing licensees.

C. Due to the prohibitive cost of, and long odds against, developing a pharmaceutical product, non-exclusive licenses of Compounds with therapeutic potential are rare because a licensee would not undertake the development without the benefit of the legal monopoly created 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 Baby Biotech has granted an exclusive license of its proprietary peptide XYZ to your client for “therapeutic use in humans but no other uses”. Suppose Baby Biotech then grants another exclusive license of XYZ to Animal Health Products for “therapeutic use in animals but not other uses”. Suppose further that your client and Animal Health Products proceed to develop the same or substantially the same formulation of XYZ and each introduces a product into the market place. Two things are certain: Animal Health has spent far less to develop its product than your client has; and the market price of Animal Health’s product is much less than the price of your client’s product. What’s to stop potential consumers of your product from buying the animal product?

D. From the licensor’s perspective, non-exclusive licensing may seem, and often is, the best way to maximize the potential value of an invention. On the other hand, a licensor must evaluate certain factors before committing to a licensing strategy. Will any prospective licensee 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? Could value be maximized by multiple “exclusive” licenses in narrowly defined fields of use? The licensor has probably committed to an irreversible strategy when it grants its first license.

E. 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 peripheral invention. With the latter, exclusivity can be obtained, even under a non-exclusive license, if the drug delivery system is used with a proprietary Compound.

F. ***Practice Tips.***

If your client is the owner of an invention, it must decide on its licensing strategy before it grants its first license because once an exclusive has been granted (unless limited by field of use or territory), it can’t grant a non-exclusive, and vice versa. A prospective licensee must undertake due diligence with respect to outstanding licenses of the same invention. While you probably will not learn economic terms of outstanding licenses, the prospective licensee needs to know what’s been granted to whom and for what uses in what territories. The prospective licensee needs to know if there is room left for its intended use of the invention. If your client is prepared to take a non-exclusive license of a compound or product (or the effective equivalent of an exclusive license with a limited field of use), negotiate for an agreement by the licensor that it restrict all other licensees from developing the same or substantially similar formulation that your client is developing. Note that this may not be possible if your client is not the first licensee. Include provisions in the license agreement that the grant of rights does not conflict with any outstanding licenses and that the licensor will not grant any licenses that conflict with

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

#### **IV. Payment Terms**

A. The economic terms of a license are, at the end of the day, matters for the business people to decide, but a good lawyer can assist the negotiations by learning what is current practice in the industry for similar inventions. Some or all of the following are common in biotech or pharmaceutical license agreements: a license or signing fee; annual or other periodic fees; milestone payments; percentage royalties, which may include minimum annual amounts; and the expenses of the patent prosecution program. 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.

B. The size of a license or signing fee, if any, is almost entirely dependent on the stage of development of the invention. From the licensor's perspective, it is a way 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 potential of 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 very hefty signing fee. On the other hand, if the licensee has been funding the research work of the licensor and the invention needs an enormous amount of development that will be funded by the licensee, it would be willing to pay only a modest license fee, if any.

C. Annual or other periodic fees are often used to incentivize the licensee to exploit the invention. These fees almost always terminate when percentage royalties (usually based on commercial sales of product) kick in. The theory is that the licensee will not be willing to pay 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 having access to the invention. In other words, the licensee is willing to pay to "shelve" the invention. Of course, this strategy only works with an exclusive license. A licensor must be aware of this possibility and negotiate annual fees that have enough bite to discourage the licensee from sitting on the invention or that reward the licensor adequately even if the invention is not exploited. Increasing annual fees are an effective device.

D. Milestone payments are very common in licenses (whether exclusive or non-exclusive) of compounds or biological materials with potential pharmaceutical applications. They are usually triggered by the typical development benchmarks for a pharmaceutical product, the achievement of which validate the value of the compound or material. The typical milestones are:

- Identification of a lead candidate for development
- Filing of IND or equivalent
- Completion of Phase I clinical trials
- Completion of Phase II clinical trials
- Completion of Phase III clinical trials
- 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”. The licensee would prefer the latter, as it would indicate that the development is progressing satisfactorily. The licensor, on the other hand, would obviously 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”, you might provide in the license agreement that commencement of the next phase of the clinical trials is deemed to evidence satisfactory completion of the preceding phase (e.g., commencement of Phase II clinical trials means that Phase I clinical trials have been successfully completed).

#### E. *Practice Tips.*

While these are business terms, the lawyer should try to learn as much as possible about the current practices in the industry. While every licensing situation is unique, there are some “industry standards”. For example, the current range for royalty rates is from about two percent for a just discovered/engineered compound or material to about 20% for a fully developed product approved for sale. See section 10 of the Sample Collaboration and License Agreement included in the Appendix for a complete panoply of license payment terms.

## V. **Drug Master File**

A. 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 cost of drug development is prohibitive (current estimates are for \$400 to \$800 million over up to ten years, on average), and therefore the drug master file has an inherent value represented by that cost. An important issue to be considered in biotech licensing is the disposition of the drug master file in the event of early termination of the license agreement.

B. A drug development project can be discontinued even if it has been successful to date. Suppose your client Pharma Company is the initial licensee of a Compound from Baby Biotech. Your client 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, your client decides to abandon the project because it has other more promising projects on its plate and insufficient resources to pursue them all. Pharma Company reluctantly decides that it must terminate the license agreement with Baby Biotech. In this scenario, Baby Biotech will likely attempt to license the Compound to a third party or pursue the project itself.

C. If you and the attorneys for Baby Biotech have done a thorough job in drafting the license agreement, this eventuality will be addressed, probably somewhere in the termination provisions, such as in section 16.5 of the Sample Collaboration and License Agreement. This “no fault” termination provision was probably the most heavily negotiated (at least in terms of time) provision of the agreement. It is an example of one possible solution to this issue.

D. Under this provision, if after a “no fault” termination of the license agreement by Pharma Company, Baby Biotech commercializes a product incorporating the Compound, Pharma Company is entitled to compensation, the amount of which depends on the stage of development at which the license agreement was terminated. The compensation is (i) a royalty on sales if Baby Biotech itself commercializes a product or (ii) if Baby Biotech licenses to a third party, a percentage of what the third party licensee pays Baby Biotech in royalties, fees, milestone, etc. and reimbursement of a portion of Pharma Company’s out-of-pocket expenses for its work. For example, if the “no fault” termination takes place during pre-clinical trials but before the filing of an IND, Pharma Company is entitled to a royalty of 1.5% on sales by Baby Biotech, and if Baby Biotech licenses to a third party, 20% of all amounts paid to Baby Biotech by the third party under the license, and reimbursement of 50% of Pharma Company’s out-of-pockets expenses incurred for the pre-clinical work. If the “no fault” termination takes place after regulatory approval of a product, the corresponding amounts are 9% 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.

E. *Practice Tips.*

Whatever side you’re representing, make sure your client considers this issue in the course of negotiating the license agreement. From the licensor’s perspective, it would like access to and use of the drug master file, ideally at no cost, under any early termination scenario. From the licensee’s perspective, it seeks some recovery of its investment in the event the drug master file benefits the licensor or a third party.

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## APPENDIX

For copies of the Appendices to this article please contact [jbm@mbbp.com](mailto:jbm@mbbp.com)

### I. Sample Collaboration and License Agreement

### II. Sample Provisions to Address the Multi-Purpose Compound