Licensing

When a company approaches BLG and states that they want to enter into a license agreement, a period of negotiation begins during which both parties work to arrive at a mutually acceptable deal. Some licenses are negotiated and completed in a manner of weeks, whereas others may take many months. Our goal is to get promising technology invented by BCM PIs into the commercial sector where it can be further developed, and to achieve this we take a practical, pragmatic, principled approach to license agreement negotiation.

The route to an executed agreement typically involves the following negotiation process:

- **Preparation of a Term Sheet**: A Term Sheet is a 1-2 page document that describes the framework of the transaction, and includes the following elements:
  - **Description of the rights being licensed**: The intellectual property rights being licensed can involve a variety of assets, including:
    - **Patent Rights**: In most cases, we will be licensing a patent application vs. an issued patent. The term sheet will incorporate description of the patent rights being licensed, which includes bibliographic information such as the serial number of the patent, the date it was filed, names of the inventors, and any patent applications that claim priority to the original application, etc.
    - **Technology Rights**: Technology rights may include tangible materials, biological reagents, data, specialized know-how or other information that the licensee may need to commercially develop the invention. We will develop a list of specific items encompassed in the technology rights that we intend to provide to the licensee.
  - **Scope of the license**: This part of the term sheet will define whether the license will be exclusive or non-exclusive, will also define whether the granted license shall be limited to specific field of use, or to a specific territory.
  - **Financial terms structure**: This section focuses on the fee structure associated with the license, which can include a combination of upfront and/or recurring fees, as well as a royalty on net sales of licensed products or services, as appropriate. Negotiation of the fee structure of a license involves compromise on both sides to arrive at an acceptable deal structure. If a company is licensing a promising preclinical, but as yet unproven technology, their focus around fee negotiation will be to defer the payment of substantial fees to the licensor until the technology is de-risked and validated. From our standpoint as a licensor, we want to receive some financial consideration early during the life cycle of the license as a demonstration of good faith and commitment. Moreover, if the licensee fails to successfully develop the technology, those early stage fees may be all that we will ever receive. As is the nature of academic inventions, most technologies we have are in the early phase of development and the licensee will have to assume large risks in the commercialization process. Because of this reality, the frequent end result is that most license fee structures are back-end loaded, meaning that fees during the early stages of the license life cycle are modest, and increase as value is added to the technology and risk is removed. It important to emphasize that each technology is
different and each deal structure will be the product of a unique negotiation.

- **Diligence terms:** Our goal with licensing is to translate innovative research discoveries into products and services that benefit patients and the general public. The incorporation of diligence terms is meant to convey expectations and to incentivize the licensee to exercise good-faith diligence with the development of the licensed technology. Diligence terms may involve targeted timelines for the achievement of developmental milestones. An example might be: “Licensee shall file an IND application with the FDA on a Licensed Product within five years of the license agreement date.” As a licensor, we’re seeking diligence terms that are clear, unambiguous and will keep the licensee moving forward.

Because the licensee stands to reap the lion’s share of the reward if commercial success is achieved (which is appropriate because they’re also assuming a great deal of risk and making a considerable financial investment), they’re typically very strongly motivated internally to move development of the technology forward. Agreement upon diligence terms is a matter of negotiation. As a licensor, we want clear and enforceable diligence terms, such that there are real consequences to the licensee if they miss a diligence target. From the company’s perspective, they don’t want to be in the situation of facing potential termination of a license agreement if they miss a diligence target, but have in fact made good-faith efforts to develop the technology. Priorities within companies can change, and if that does happen, the company can opt to terminate the license agreement.

The incorporation of an annual maintenance fee in to the financial structure of an agreement can provide an incentive for the licensee to continue developing the technology. If the company has to write a check each year in order to maintain the license, they are in the position of having to make a financial decision about holding on to the license on an annual basis.

- **Agreement on the business terms and license framework presented in the term sheet, followed by preparation of a draft license agreement.**

Once a term sheet has been developed, both parties will negotiate over the business and diligence terms and arrive at a mutually acceptable framework that will be incorporated into a full draft license agreement. We strongly prefer to use our license agreement templates as starting points because we own the intellectual property that is being licensed. Once drafts have been exchanged, additional negotiations over the terms of the license agreement will commence.

The negotiation period is variable, and is typically shorter for non-exclusive research tool licenses, and longer for exclusive agreements involving rights to therapeutics, devices, or vaccines. The negotiation period depends heavily on the negotiating partner on the other side of the table. In many cases, companies will send a draft license agreement to their legal counsel for review. If the
company’s legal counsel has experience working with academic institutions and understands their concerns, the negotiations may proceed smoothly. If not, it can be a very different story and negotiations can drag on, which is never our goal. However, we are charged with protecting the interests of the college and there are times when the other party may insist that we agree to terms that we believe may be harmful to the interests of the college, and resolving these issues can be challenging. The point is to end up with a mutually acceptable deal that gives both parties sufficient incentive to move forward. Unbalanced, asymmetric deals that unacceptably favor one side over the other never work out well in the long run. So long as there is sufficient will to execute a deal on both sides of the table, and both sides stand to gain from reaching agreement, agreement will be reached. Each license agreement is the product of a unique negotiation – no two are exactly the same.

- **Legal review and signature of the license agreement.**

  Once agreement on license terms and language has been reached, the draft agreement will be sent to the BCM Office of General Counsel (OGC) for legal review. This legal review process focuses on license agreement terms that could potentially expose the college to undue risk, etc. BLG project managers have experience working with OGC, so in most cases if there are questions about particular agreement terms, those questions are addressed and resolved prior to the agreement being submitted for final review. After the agreement passes OGC review, it is forward to the Sr. VP for Research for signature on behalf of BCM. Following signature by BCM, the agreement is forwarded to the company for final execution. Once both sides have signed the agreement, the deal is fully-executed.

- **Types of license agreements**
  - **Exclusive licenses.**
    These agreements involve a license of intellectual property rights to a single company, and typically involve a patented asset – a therapeutic (drug, biological, method, or some combination), a device, or a vaccine. The licensee is granted the exclusive right, often with the right to grant sublicenses, under patent and technology rights owned by BCM, to make, have made, use, market, sell, lease, and import licensed products in the field of use. The license grant that we confer to companies allows their commercial exploitation of the technology. However, the exclusive license grant is restricted and non-exclusive with respect to the following terms:

    - **BCM will always retain the right (for itself and others) to use the licensed patent rights and technology for non-commercial research and education purposes, as we can’t accept terms in a license agreement that impede or restrict the ability of the PI to continue their academic research. If, however, the technology being licensed is in clinical development, the licensee may insist that they have the right to approve any clinical use of the licensed technology in the academic setting. The reason for this is that if clinical use of the technology in the academic setting were to result in an adverse event, it could derail the company’s commercial development efforts and would be very costly to the company.**
    - **If the licensed technology was funded by the federal government, we will stipulate that the government has a non-exclusive right to use the invention by or on behalf of the United States. This is a statutory requirement mandated by the Bayh-Dole Act.**
Financial consideration in an exclusive license: Financial terms in each license agreement are a product of negotiation and can vary widely from deal to deal. The following elements are frequently found in exclusive licenses:

- **Upfront payment**: Due upon execution of the license.
- **Annual maintenance fee**: Due upon each anniversary of the license agreement.
- **Milestone fees**: Fees that are payable upon the successful achievement of a commercial development milestone, for example, the initiation of a phase II clinical trial of a licensed product. When a licensee achieves a milestone event, they have an obligation to report the event to the licensor and accompany it with the appropriate payment.
- **Royalties on net sales**: Royalties are recurring payments (typically quarterly) based on a percentage of net sales by the licensee.
- **Other fees** or variations on the fees listed above may be a part of the deal.
- **Equity**: BCM does accept equity in license agreements to start-up companies. Start-ups are typically cash-poor and cannot afford extensive cash fees at the outset of the license life cycle. They’re trying to raise money, not spend it. Most deals that involve equity also have cash fees (milestones and royalties) associated with them, so that the prospect of receiving consideration from the licensee isn’t solely dependent on the equity becoming liquid. Equity is distributed under the terms of Patent Policy in the same manner as cash consideration, meaning that as a faculty member if the license involves equity as part of the compensation package, you will receive your shares upon issuance (usually shortly after execution of the license). Your shares will be yours to manage, and any decision to sell or dispose of your shares will be yours – the college will manage its shares independently.

Other key elements of an exclusive license agreement:

- **Indemnification**: BCM requires its for-profit licensees to indemnify the college and its personnel against any third party legal actions that may arise out of the licensee’s activities under the license agreement. This is an issue that is critically important to the college. If a licensee attempts to change the indemnity provisions of the agreement to shift risk in the college’s direction, this can produce delays with concluding an agreement.
- **Insurance**: BCM requires its licensees to carry adequate insurance protection that is appropriate for the type of product being developed and/or marketed by the company.
- **Management of infringement actions**: Describes how the licensee and licensor will address any actions related to third-party infringement of the licensed patent rights, and describes how any infringement-related settlement will be allocated among the parties.
- **Term and termination**: Defines the lifespan of the license (for a patented technology, the deal will typically expire when the last-to-expire patent claim expires in a particular country). This section also defines the circumstances under which BCM as a licensor can terminate the licensee. Our right to terminate is typically linked to a breach by the licensee that is not cured within a specified period of time. The for-profit licensee can terminate the agreement with or without cause. If the company decides that their strategic priorities have changed and they no
longer wish to develop the technology that they licensed from BCM, they may elect to terminate the deal.

- **Non-exclusive license agreements.**
  These license agreements involve technologies that are licensed to multiple companies, and most frequently confer rights to non-patented research tools, such as knockout mice, cell lines, antibodies, and the like. The license grant will often be restricted to research use (frequently the case with mouse licenses), or the license may convey the right to sell the licensed technology to third parties (as may be the case when we license an antibody to a distributor of life science research reagents).

  - **Financial consideration in a non-exclusive license:**
    - **Upfront payment:** Once the upfront payment is received, the PI is provided with instructions for shipping the material to the licensee. In some cases, compensation for research tool licenses may be limited to a single up-front payment, if appropriate. Most research tool licenses will involve an upfront payment and an annual maintenance fee.
    - **Annual maintenance fee:** This fee, as the name implies, is payable upon each anniversary of the agreement, typically for the duration of time that the licensee intends to use the tool.
    - **Royalty on net sales:** This recurring fee is applicable in cases when a tool is licensed to a distributor of life science reagents for resale to their third party customers (often the case with antibodies). As a matter of practice, we do not seek “reach-through” royalties on products that are developed with the use of our tool. For example, if we license a mouse model to a pharmaceutical company for use in their drug screening efforts, we would not expect to receive a royalty on any compound that touched the licensed mouse at some point during the drug development process. Seeking a reach-through royalty associated with the use of a tool is a “non-starter” for pharmaceutical and biotech companies, and is a mechanism to insure that a deal won’t get done. The company will walk away and find another route to get what it needs.
    - **Lack of patent costs:** Because research tools are almost always not patented, there are no patent costs to reimburse before license revenue distribution to the PI, department, and BCM General Fund can take place. For popular research tools, the revenue stream to the PI can be significant.

- **Inter-institutional Agreements (IIAs)**
  We live and work in a collaborative world, and technologies are frequently developed that are co-owned by two (or more) academic institutions. In order to successfully commercialize a co-owned technology, academic institutions will frequently negotiate an inter-institutional agreement (IIA) to put the technology transfer office of one of the owners in the “driver’s seat” with regard to the management of licensing and patent strategy. The institution that assumes the lead commercialization role typically has the authority to coordinate patent prosecution strategy and to negotiate a license agreement on behalf of both institutions. The institution that takes the lead role is normally the one that owns the majority of the jointly-owned technology. The parties to the IIA will agree upon patent expense sharing and license revenue sharing and these percentages almost always coincide with each institution’s respective ownership percentages in the invention. In most
cases, the negotiation and management of IIAs is a collegial process, as it should be given that both academic owners of the technology want to see it successfully commercialized.

IIAs are done to facilitate more efficient commercialization of jointly-owned inventions. If a company had to negotiate a separate license agreement with each academic institution that had ownership rights to an invention, they might simply choose to walk away rather than deal with the transactional complexity of completing multiple deals to sew up rights to the invention.

- **Distribution of license agreement revenue**

  The license revenue distribution scheme at BCM is defined in Section V of the BCM Patent Policy (BCM Policy Manual, “Inventions & Patents”, Policy 20.8.1). The distribution scheme is as follows:

  Gross license revenue – 15% BLG allocation – unreimbursed patent costs = Net Income

  1. 15% of gross license revenue is allocated to BLG to support the cost of our operations.
  2. Any unreimbursed patent costs are paid back. We attempt to negotiate repayment of past patent costs by licensees, but this is a matter of negotiation.
  3. Arrive at Net Income
     a. 40% of Net Income is allocated to the developers according to the percentages listed on the disclosure form.
     b. 30% of Net Income is allocated to the department/center where the technology was developed. Note: If a PI has academic appointments in multiple departments at BCM, it will be important for the PI to identify the appropriate departmental affiliation for the disclosed technology, so that the departmental share of license revenue can be correctly allocated.
     c. 30% of Net Income is allocated to the Baylor General Fund.
The license revenue distribution policy at BCM is consistent with best practices across academia. Generally, academic revenue distribution policies divide license revenue among the inventors, the department, and an institutional research fund, but there is broad spectrum at play. BCM’s policy fairly recognizes the role of the inventor, as well as the support of the department and the institution. The college fronts patent costs and coordinates patent prosecution activities, so there is no risk to the inventor associated with these activities. In contrast with their academic colleagues, industry scientists generally do not directly share in the revenue that their invention(s) produce for their employer. When a BCM invention is successfully commercialized, everybody wins.

In case of a jointly-owned technology, license revenue will be shared with the other institution, normally at a level that is proportional to the other institution’s ownership interest. If required in the funding agreement, we may also share license revenue with non-profit foundations and other research sponsors, and here the revenue sharing percentage is typically in alignment with the degree to which the foundation’s funding was used to support the development of the licensed invention.

- Post-license agreement management
The execution of a license agreement should not be thought of as an ending, but rather as the beginning of a long-term relationship. During the course of that relationship, there are several parameters that are monitored by BLG:

- **Timely submission of payments**: BLG monitors licensee payments and notifies licensees when they are late. When interest is owed, we notify them that the owe interest as well. Many licensees require that BLG prepare and submit an invoice for payment, which we do. We do have recourse if a licensee does not pay, leading up to and including termination of the license agreement.

- **Achievement of diligence milestones**: BLG monitors the progress of our licensees as they work to develop from products and services from the licensed technology. Licensees don’t always hit their diligence targets, and in fact, “misses” are frequent. Developing products based on biological technologies is often a very complex, time-consuming process, and despite a licensee’s best efforts, they may miss a diligence target. Our key goal is to insure that the licensee is indeed exhibiting a good-faith effort to develop the technology and move it forward.

- **License amendments**: An executed license agreement is a binding legal agreement between the parties. That being said, because license agreements govern long-term relationships and the parameters that impact a license agreement can change during the life cycle of the agreement, it is can be necessary to amend limited terms for a compelling reason and upon mutual agreement between BCM and the licensee. Amendments may be necessary to add new intellectual property to the list of licensed IP, to change a diligence target, or to change the financial terms of an agreement. A company may encounter a situation in which they are no longer able to meet the financial obligations associated with the license agreement, and they may wish to renegotiate to avoid possible termination of the agreement. If it makes sense for the commercial prospects of the underlying technology, then we may agree to renegotiate the financial terms of a deal, but any such renegotiation must make sense for BCM, and well as the licensee.