Advanced Licensing Agreements 2017

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Licensing in the Life Sciences Industry

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I. INTRODUCTION

Licensing plays a critical role in the operations of life sciences companies, and virtually all life sciences companies rely on licensing arrangements to achieve their business goals. These licensing arrangements may include the licensing of intellectual property rights between companies for the research and development of pharmaceutical products, licensing of special manufacturing techniques to more efficiently make products that companies develop and commercialize, or licensing of already developed products for commercialization in a different market. In recent years companies have entered into more complex deals involving baskets of rights, potential added assets, and/or assets being contributed from both sides.

II. DIFFERENT TYPES OF AGREEMENTS THAT MAY LEAD TO LICENSE AGREEMENTS

A. Non-Disclosure Agreement (NDA) / Confidential Disclosure Agreement (CDA)

1. A CDA (or NDA) is a crucial precursor to the negotiation process for any license agreement to protect any information that may be disclosed in the negotiation process, and also to ensure that the discussions and negotiations (including the fact that any discussion/negotiations are taking place) between the parties remain confidential.

2. Key considerations in drafting a CDA
   a. Determine whether the CDA should be unilateral or mutual.
      i. In most cases, a mutual CDA will be the more appropriate approach, since the parties will likely be exchanging confidential information during the negotiations and initial due diligence. A mutual CDA should also be used in situations where there may be significant collaboration between the parties.
      ii. In certain cases, a mutual CDA may not be required, for instance, where the licensing negotiation involves a discrete technology transfer for one-time consideration and very little ongoing collaboration or information sharing.
b. Identify the purpose of the CDA.
   i. A CDA typically provides that the confidential information may be used in connection with a particular purpose, for instance to discuss and negotiate the terms of the transaction or to perform initial due diligence.
      (a) Where the negotiations conducted under a CDA ultimately leads to a definitive license agreement, the parties should strongly consider including separate confidentiality provision in the license agreement (rather than rely on the CDA).

c. Define “Confidential Information.”
   i. Generally, the definition of “Confidential Information” may include a broad range of different types of information (i.e. proprietary information, financial information, customer information, etc.).
      (a) A more narrow approach is to define “Confidential Information” as only that information which is (1) marked “confidential”, (2) disclosed orally and identified as being confidential at the time of disclosure, and thereafter summarized in writing and confirmed to be confidential in writing, and/or (3). Information any person familiar with the technology or industry would reasonably expect to be confidential under the circumstances.
   ii. In determining what will constitute “Confidential Information,” it is important to also consider any exceptions or permitted disclosures.
      (a) For example, typical exceptions to “Confidential Information” may include:
         (1) Information already available in the public domain.
         (2) Information already known to the receiving party or otherwise disclosed to the receiving party, provided such information was not received as a result of a
breach of any agreement or obligation between a third party and the disclosing party.

(3) Information that can be demonstrated, subsequent to disclosure, to be independently developed by the receiving party without use of any confidential information received from the disclosing party.

(b) For example, typical permitted disclosures may include information required by law to be disclosed.

(1) Frequently, this exception is included with certain conditions that require the receiving party to give prompt notice of a request for any disclosure of the disclosing party’s confidential information, and cooperation from the receiving party in taking efforts to quash any such disclosure, or seek a protective order (as appropriate), or in the event that the parties are unable to prevent any such disclosure requiring that the receiving party limit the disclosure to the maximum extent possible.

d. Obligations to protect and return Confidential Information.

i. To address instances where the return of Confidential Information is not feasible, parties may include an additional obligation to destroy the Confidential Information, and issue the disclosing party a certificate (signed by a duly authorized representative of the receiving party) evidencing destruction of the Confidential Information.

e. Other Issues to Consider

i. Duration of confidentiality obligations

ii. Whether the confidentiality obligations should extend to cover a party’s affiliates and third party advisors
iii. Whether a standstill clause (preventing each party from purchasing the other’s stock or commencing a takeover bid against the other party) is required

iv. Governing law

B. Letter of Intent

1. A letter of intent is typically used by universities and is a short agreement intended to permit the filing of a patent application in exchange for a first right of negotiation.

2. In a corporate agreement, a letter of intent in the form of a right of first negotiation may be used as part of a larger agreement.

3. Generally, actual financial terms are not included in a letter of intent.

C. Term Sheet

1. In many cases, (after a CDA has been executed), a term sheet will be the first step in opening negotiations in a particular deal. The term sheet should be limited to business terms, including:
   a. Intellectual property covered (patents, trade secrets, copyright, trademark, biological materials)
   b. Exclusivity/Field of Use
   c. Upfront Payments
   d. Milestone Payments
   e. Annual fees and patent costs
   f. Royalties on sales of “Licensed Products”
   g. Diligence (research and development and/or commercialization efforts/rights)
   h. Equity (if applicable, although this is usually addressed in a separate term sheet).

2. In certain cases, a term sheet may accompany a letter of intent.

D. Evaluation and Option Agreements

1. These agreements allow a party access to the technology for the purpose of evaluating whether to enter into a more extensive agreement for the technology on pre-agreed terms or on terms to be negotiated. Such rights are generally time limited
so that the licensor can consider alternatives if the option holder decides not to exercise the option or if the parties cannot come to a definitive agreement.

2. Often, the terms of the license are attached to the option.

E. Material Transfer Agreement (MTA)

1. These agreements are similar to any other technology transfer agreement in that they address transfers of certain rights, titles and interest in research materials, such as compounds, reagents or cell lines, between two or more parties. These arrangements often cover situations where a transfer is used by a transferee for further defined research goals or development objectives. Academic institutions, research organizations and industry regularly enter into these arrangements.

III. DIFFERENT TYPES OF LICENSING AGREEMENTS

A. Sponsored Research Agreement (SRA)

1. A SRA governs the contractual relationship between a party paying for the research, and a party (presumably one with expertise in the subject matter) performing the research.

2. Different types of SRA arrangements:
   a. industry – university arrangements, where typically, a university or other non-profit institution performs research paid for by a company.
   b. industry – industry arrangements, where typically, a small biotech company performs research paid for by a big pharma (or biotech) sponsor company.
   c. industry - government arrangements, where typically, a government agency/department performs research paid for by a company.
      i. In the United States, this is typically in the form of a Cooperative Research and Development Agreement (CRADA). Private companies participating in a CRADA are allowed to file patents on the subject technology, and retain patent rights on any such inventions developed under the CRADA, while the government gets a license to such patents.
B. Collaborative Research Agreement / Joint Development Agreements

1. Under these types of collaborative agreements, two companies enter into an arrangement to collaborate in development of a product calling for special resources of each company. Often, each company will need to use some of the technology of the other in the course of such development.

C. Clinical Trial Agreement (CTA)

1. A CTA determines the contractual relationship between a Sponsor (entity paying for the research), and the Investigator (entity conducting the research), and governs the administrative/legal terms under which a clinical (human) trial/study, which is a prerequisite to regulatory approval of a new pharmaceutical product or medical device, will be conducted.
   a. In certain cases, a Sponsor may enter a contract with a Contract Research Organization (CRO), and the CRO will have agreements with various Investigators to conduct the research (clinical trials).

2. A typical CTA contains several provisions dealing with rights regarding:
   a. Publication of research data;
   b. Confidential information;
   c. Ownership and use of research data;
   d. Ownership of intellectual property;
   e. Indemnification;
   f. Insurance; and
   g. The Generic Drug Enforcement Act.
      i. When a drug company applies for FDA approval of a drug, it must submit a certification that no individuals who have been debarred, under the Generic Drug Enforcement Act of 1992 (GDE), participated in the preparation of a drug application under 21 U.S.C. § 355(b) or (j). Therefore, CTAs typically include a clause which required a certification that the Principal Investigator and other participating in the study are not debarred, and have never been debarred, under the GDE.
IV. GRANT OF RIGHTS

A. Limited License

1. License grants may be limited by many aspects of grant such as time, field of use, geography, or existence of certain preconditions or occurrence of certain specified events. The following are examples of factors that restrict the licensing rights of life science technologies:

   a. Field of Use
      i. A technology can be licensed for virtually any application, but technologies can also be licensed for limited uses, both for specific indications (such as discrete therapeutic treatments) or broader categories (such as human use). Sometimes a strategy of multiple licensing arrangements for multiple fields of use increases the overall value of the technology to the licensor

   b. Geographic Territory
      i. A license can be restricted to a specific geographic territory
      ii. Early stage research agreements are less amenable to geographic restriction since the incremental value is in the research and development.
      iii. Obtaining regulatory approvals and marketing a product, may require geographic specific expertise.

   c. Exclusivity
      i. Non-Exclusive – rights granted to the licensee may also be granted to others.
         (a) A non-exclusive license is often used in reagent licenses where various companies are given rights to sell or use research reagents. It is also used in licensing drug discovery rights and genomic databases.
      ii. Exclusive – rights granted to the licensee may not be used by others (generally, “others” includes the licensor).
(a) An exclusive license is appropriate when the final FDA-approved product is covered in the license.

(b) Companies that develop technology (methods or materials) used in the discovery, research or development of biopharmaceutical products (“Research Tools”) will often license in research tools on an exclusive basis from universities when the Research Tools will be critical platform technologies for the company.

d. Improvements (and Patent CIPs)
   i. While companies will seek a broad set of IP rights, including rights to any improvements developed under a license agreement, universities will generally restrict or limit any license to improvements.

B. Grant-Back
   1. Under a grant-back obligation, the licensee agrees to grant a license to the licensor for any improvements that the licensee has made to the licensed technology.
   2. Grant-back licenses may give (i) exclusive rights to use future improvements (A) solely to the licensor, (B) to both parties to share those rights to the exclusion of others, or (ii) non-exclusive rights to use future improvements to both parties, allowing each to grant licenses to others to use such improvements.
   3. Consider antitrust issues surrounding the possible anti-competitive effects of grant-back clauses.

C. Sublicensing
   1. Generally, a sublicense amounts to a grant by a licensee of certain licensed rights to a third party, the sublicensee.
   2. The rights granted to the sublicense cannot be broader than the rights granted to the licensee by the licensor under the terms of the master license agreement. Within the bounds of this basic restriction, however, the scope of the sublicense can be contractually limited or shaped as agreed by the licensor and licensee. The parties may therefore permit a partial or complete sublicense of a party’s interest in a license
D. Assignment

1. Partial or complete assignment of a party’s interest in a license is also possible. An assignment differs from a sublicense in that the sublicensor retains an ongoing interest in the license and the license can revert to the sublicensor under specified circumstances, such as with the bankruptcy of the sublicensee. In the case of assignment of a licensee’s interest, however, the contract relation between the licensor and the licensee ends to the extent of the assignment, unless the licensee guarantees the obligations of the assignee under the license.

V. GOVERNANCE

A. Needed to manage the relationship between the parties and to ensure a clear decision making process

B. Joint Steering Committee (“JSC”)

1. Should include a specified number of members from each party, and typically identify one chairperson of the JSC.
   a. The chair person will typically be responsible for making tie-breaker votes.

2. Roles and responsibilities should be defined
   a. Amongst other things, the JSC will typically be responsible for
      i. Agreeing on the research plan
      ii. Reviewing goals and strategies of the collaboration
      iii. Facilitating technology and/or information transfer
      iv. Receiving deliverable under the research plan
      v. determining any changes in research direction or revisions to research plans
      vi. Reviewing publications
      vii. Reviewing and allocating financial and personnel resources
      viii. Resolving disputes
      ix. Determining whether milestones have been met and/or finalizing milestones
x. Deciding on size, number, or type of clinical trials

xi. Dealing with field of use limitations (territorial, indications) – if one has split territories or indications may impact the other party

xii. Deciding on early termination e.g., due to research failure, change in business directions, etc.

b. The JSC is also usually tasked with making safety-related decisions.

c. The JSC may appoint sub-committees
   i. Joint Research Committee (“JRC”)
   ii. Joint Development Committee (“JDC”)
   iii. Joint Clinical Committee (“JCC”)
   iv. Joint Commercialization Committee
   v. Other subcommittees for specialty topics such as IP, Regulatory and Finance
   vi. Working Groups / Joint Project Teams

3. Members of the JSC should understand the science, the company business, and have the time to participate
   a. principal investigator or chief scientist, preferably someone who has already invested into the program so has buy-in

4. Governing Strategy
   a. Top down – JSC determines the research work and tells the “team” what they are going to do – the challenge with this strategy tends to be in the failure to explain to the “team” why they are doing what they are doing (e.g. less buy-in)
   b. Bottom up – team provides recommendations for moving forward (i.e. more buy-in to the project), and the JSC makes the final decisions

5. The JSC provision of the license agreement should include:
   a. Composition of the Committee
   b. Meetings
      i. Determine number (frequency), times, and locations of the meetings
ii. Allocation of cost (expenses incurred in participation)
c. Dispute resolution process - voting, veto, escalation, and tie breaking rights
d. Instructions regarding preparing/finalizing the research plan/development plan/work plan
e. Definition of areas of joint control and divided responsibilities e.g., allocate regulatory and compliance issues

6. Governance factors that typically contribute to failure of the relationship
   a. JSC or subcommittee membership changes
   b. Lack of accountability

VI. DILIGENCE OBLIGATIONS

A. While diligence obligations are rare in simple non-exclusive licenses (because the licensor can always extract additional value from the IP by granting additional licenses), diligence obligations are important to a licensor granting an exclusive license that is not fully paid because, in the absence of diligence, the licensee might shelve the product and the licensor would never receive those additional payments that are dependent upon developing or selling the product

1. Substantial license maintenance payments may be a substitute for diligence but life sciences licensees are frequently hesitant to agree to large license maintenance payments due to the uncertainty surrounding if/when the product will receive regulatory approval, the scope of the label, and pricing/reimbursement issues.

B. Examples of licensee’s diligence obligations:
   1. Obligation to diligently market and sell (which may be subject to obtaining regulatory approval)
   2. Obligation to diligently obtain regulatory approval (which will require having an adequate amount of data meriting regulatory approval)
   3. Obligation to diligently perform testing to obtain data sufficient to obtain regulatory approval (which may be subject to unforeseen obstacles and delays)
4. Obligation to diligently achieve anything else that results in a payment to licensor

C. Examples of licensor’s diligence obligations:
   1. Licensor may also have diligence obligations such as smooth and timely transfer of technology, know-how, regulatory registrations/licenses, data, etc.

D. Diligence Standards
   1. To avoid ambiguity, consider specifying any “efforts” standards used in a license agreement as defined terms describing what sort of actions would satisfy such diligence requirements.
      a. Example definition (relying on promisor’s past practice):
         i. “Reasonable Efforts” means, with respect to a given goal, the efforts, consistent with its past practice, that a reasonable person….”
      b. Example definitions (relying on practice in a given industry):
         i. “Reasonable Efforts” means, with respect to a given goal, the efforts, consistent with the practice of comparable pharmaceutical companies with respect to pharmaceutical products of comparable market potential, that a reasonable person….”
         ii. “Commercially Reasonable Efforts” means, with respect to each Party, the efforts which would be used by such Party in connection with comparable internal projects of similar nature, value and status, which in no event will be less than those generally used by a company of similar size and resources as such Party at the time such efforts are required, with respect to a product or potential product at a similar stage in its development or product life, taking into account product labeling, market potential, medical and clinical considerations, the regulatory environment, financing environment, patent and other proprietary position and competitive market conditions in the therapeutic area, all as measured by the facts and circumstances at the time such efforts are due.
2. “Commercially Reasonable Efforts” versus “Best Efforts” versus “Commercially Reasonable Best Efforts”
   a. There is no basis for suggesting that “reasonable efforts” should be given a meaning different from “best efforts,” “commercially reasonable efforts,” or “reasonable best efforts”; and most courts use the terms interchangeably. See, e.g., Trecom Bus. Sys. V. Prasad, 980 F. Supp. 770, 774 n.1 (D.N.J. 1997)(stating in the context of an implied “best efforts” provision that whether one uses the term “best efforts” or “reasonable efforts” is “merely an issue of semantics”).
   b. In fact, some courts have described “best efforts” as an ambiguous standard. See, e.g., Martin v. Monumental Life Ins. Co., 240 F.3d 223, 233 (3d Cir. 2001) (“‘Best efforts’ has been widely held to be an ambiguous contract term”).
   c. It may be worth noting, however, that at least one court has held that “best efforts” is a more stringent standard than “reasonable efforts.” See In re Chateugay Corp., 198 B.R. 848, 854 (S.D.N.Y. 1996), aff’d 108 F.3d 1369 (2d Cir. 1997)(“The standard imposed by a ‘reasonable efforts’ clause such as that contained in section 7.01 of the Agreement is indisputably less stringent than that imposed by the ‘best efforts’ clauses contained elsewhere in the Agreement”).

E. Objective Diligence Criteria
   1. An absolute obligation to achieve a particular goal by a particular time.
   2. Examples of objective Diligence Criteria:
      a. Initiating clinical trials by specified dates
      b. Filing for regulatory approval within a certain time after completing a pivotal clinical trial.
      c. Filing for pricing approval within certain time after completing a reimbursement study.
      d. Launching the product within a certain time after receiving the necessary approvals.
      e. Employing a specified number of sales representatives.
3. Some flexibility may be applied in setting objective diligence criteria. For example:
   a. Providing mechanisms for getting extension of time.
   b. Providing a buffer between breach and termination.
   c. Making obligation to use good faith diligent efforts to achieve a particular goal by a specified time.
   d. Making money a surrogate for diligence, for example, by:
      i. specifying a threshold minimum spend on the research program is evidence of diligence (while keeping in mind that appropriate spending varies according to stage of development/commercialization); or
      ii. requiring minimum (royalty) payments to licensor to avoid termination, creditable against next milestone.

VII. IP TRANSFER / TRANSITION SERVICES

A. Transfers (or transition services) may be necessary if the license isn’t just for patent rights, but for all rights to a pharmaceutical product/program and such rights may include know-how, biological materials, regulatory approvals, contracts, manufacturing rights/access and more.

B. Degree of complexity varies with the maturity of the product/program.

C. Determine when transfer from licensor to licensee will occur:
   1. right after license agreement is signed, if licensee will do all work post-signing.
   2. later if the agreement contemplates a period in which the licensor conducts research or development and the licensee takes over after the end of such period.

D. Transfer back from licensee to licensor happens after the agreement terminates.
VIII. CONSIDERATION

A. Upfront Fee(s) / Payment(s)

1. Upfront payments are amounts payable upon execution of the license, or shortly thereafter.

2. Upfront payments are usually a small portion of the overall license consideration, especially with earlier stage technology.
   a. Generally the more mature the science or technology, and therefore less perceived risk to commercialization, the greater leverage a licensor will have to obtain a significant upfront fee from a licensee.

3. A licensor generally prefers an upfront payment to be as large as possible for a number of reasons, including the following:
   a. Many life science companies are operating under enormous fiscal constraints and need immediate infusions of cash to continue as viable commercial enterprises. Funds for research and development, clinical trials and regulatory submission are required as a precursor to any cash flow activities.
   b. The licensor may lose control over the commercialization process and cannot be certain it will obtain all or any of future or contingent payments.
   c. Non-contingent upfront payments usually can be recognized immediately as revenue under applicable accounting rules. Recognizing such revenue can add credibility to a licensor’s technology and business plan and help raise additional funding through venture capital or private equity channels. In many cases, an immediate cash influx can increase the valuation of the licensor company, which in turn will assist the licensor to raise additional capital at higher valuations and reduce its overall cost of capital.
   d. A significant upfront fee provides the licensor tangible proof of the licensee’s strategic interest in the licensing arrangement and its further commitment to develop and commercialize the technology. A large upfront fee demonstrates the licensor’s genuine commitment to the project,
rather than just a one-time payment for an “option” to the technology at a later date.

4. The licensee itself may also prefer upfront payments under certain limited circumstances, such as when it can improve its accounting of the licensing transaction by capitalizing all, or a portion, of any upfront payments, avoiding future drags on its income statement arising from significant royalty payment obligations.

   a. This may be especially the case when the licensing transaction is part of a broader corporate restructuring, tripartite party licensing and sublicensing arrangement, or the buying or selling of a related business. In most cases, however, licensees resist paying large upfront fees.

5. Upfront payments can also be structured to act as interim funding mechanisms for licensors. For instance, upfront payments can be effectively limited or unlimited recourse loans (cash flow bridges) from the licensee to the licensor. One example is where the upfront payment can be characterized as a creditable deposit towards future milestone, royalty or cost of good payments. Although these mechanisms do not change the nature of the consideration and its accounting treatment for both the licensee and licensor, they can radically alter the cash flow profile to the parties and assist the licensor in solving its short term cash flow objectives. In these instances, the licensee may well request a right to claim a security interest in the technology should the milestones not be obtained or royalty payments not materialize by a specific period of time.

B. Royalties

1. Royalties typically represent the most important financial element of a life science license, and the most significant revenue stream to the licensor. Royalties can take many different forms and there is a wide range of negotiated royalty rates, depending on the type of technology, maturity of the underlying science and the product market, and the other terms of the agreement between the parties, including, the amount of consideration paid to a licensor through upfront fees and milestone payments.

   a. Royalties are usually periodically paid upon the commercialization of a technology, and may be distinguished
across different territories (i.e. on a country-by-country basis).

b. Calculation of royalties is often based on “Net Sales” of a product.
   i. Deductions from “Net Sales” calculations should be itemized, and may include, for example:
      (a) Ordinary and customary trade discounts
      (b) Credits, rebates and product returns/recalls
      (c) Transportation, freight and insurance discounts
      (d) Duty and taxes
      (e) Manufacturing costs
      (f) Marketing costs
      (g) Other reasonable estimates for price reductions/adjustments and similar allowances.
   c. Calculations of royalties may, in the alternative, be based on “Net Profits,” but this can be problematic because profit figures can vary tremendously depending on accounting practices.

2. Some of the factors that may influence royalty rates include:
   a. Whether the license granted is exclusive, sole or non-exclusive.
   b. The market sector for the product.
   c. Stage and costs of research and development of the product.
   d. The licensor’s role and involvement in the continued research, development or commercialization of the product.

3. In some cases, Minimum Royalties may act a mechanism of ensuring the licensee actively commercializes, rather than shelves, the licensed technology. It requires the licensee to make such payments or alternatively default and have the license terminate.

4. Other Royalty Considerations:
   a. Royalty stacking – a deduction from royalty payments owing to the licensor of all or a portion of royalties
payments owing to third parties in relation to the technology.

b. Reduced Royalties on the occurrence of certain events:
   i. Generic Entry – when a generic version of a product is commercialized, or reaches certain sales levels.
   ii. Competing products are commercialized.
   iii. Patent Expiry
       (a) To avoid potential patent misuse issues, in cases where hybrid licenses are granted (i.e., where both patents and know-how are licensed), parties should consider including a “step-down” royalty – a decreased royalty rate that comes into effect upon the expiration of the patents.

5. Audits
   a. Set the timing and notice provisions (i.e., how much time the licensor is required to give the licensee as notice of an audit)
   b. Determine how underpayments found by the audit will be (i.e., interest rates and audit costs)
   c. Set the period for which licensee must keep all records relating to the license

6. Profit shares (typically considered in co-commercialization or joint venture agreements)

C. Milestone Payments

1. Milestone payments are payments made by the licensee to the licensor at pre-determined times in the development of the technology or upon the occurrence of certain pre-agreed events or achievements, such as the approval of a licensed product for an indication in a specific territory, or the completion of a phase of clinical trials. Milestones in life science licenses can be structured as follows:

   a. Periodic payments (such as monthly, bi-annually or yearly payments) regardless of whether the technology is successful or commercially exploited. This assures a licensor certain minimum revenues whether certain achievements
are reached, while the licensee has time to attain certain achievements at its own pace.

b. Milestones based on commercial achievements.
   i. Milestone payments upon achievements of certain revenue thresholds.

c. Research & Development Milestones
   i. Regulatory (i.e. IND/NDA filing and/or obtaining regulatory approval)
   ii. Pre-Clinical
   iii. Phase 1
   iv. Phase 2
   v. Phase 3
   vi. Phase 4

D. Sublicensing Income
   1. Royalties payments from sublicensees
   2. In certain cases, the parties may also want to include non-royalties sublicensing income.

IX. LEGAL PROCEEDINGS

A. Dispute resolution mechanisms must have clear timelines for resolution and procedures for discovery and submissions. In an effort to avoid costly litigation, parties should consider the following dispute resolution mechanisms:
   1. By Senior Executives
      a. Agreements may include clauses that provide a reasonable initial 30-60 day period whereby senior management attempt to resolve any dispute before triggering a formal arbitration clause and/or litigation.
   2. Mediation
      a. Mediation, a voluntary non-binding, less formal dispute process, can be a useful dispute resolution tool. It is consensus focused and can be flexible and easily customized for specific situations. However, since the parties need to agree to a solution, there is no certainty that there
will be a final outcome. For parties that wish to reduce the costs and time involved in reaching a final resolution, mediation is often considered an extra step before litigation. If the parties’ senior management has attempted to resolve the disputes prior to ADR, mediation may have limited benefits.

3. Arbitration

   a. Arbitration is the most common form of commercial dispute resolution in license agreements. There are numerous advantages to arbitration. It is generally more private and informal than litigation. Parties can select a decision-maker who can understand the technical aspects of the dispute which is especially important if involves scientific matters. Arbitration is perceived to be less biased than a jurisdiction specific court, less adversarial than litigation and increases the chances parties can preserve trust and business reputation during the dispute. It is flexible (the parties can choose a mutually acceptable third party arbitrator) and the arbitration tribunal’s powers and scope of decision-making can be spelled out in as much detail as the parties require. Institutional arbitration may be preferable if trust is eroded between the parties. A more ad hoc process may be preferable if trust is still high.

   Arbitration does, however, have disadvantages. Like litigation, the arbitration decision may produce a clear winner/loser. It is also less useful for operational disputes where extremely quick resolution is desirable. Its availability may encourage licensing parties to exaggerate claims on the belief that arbitration is biased towards “splitting the difference”. If the right is available, the license runs the risk that one party may repeatedly rely on it and burden the licensing arrangement with many matters that distract the parties from their focus if it is viewed as less of a deterrent to escalating frivolous disputes than litigation where a party risks greater expense and publicity. Although arbitration is generally less expensive than litigation, it can still be costly. Furthermore, appeal routes are either not available in binding arbitration or more limited than in litigation.
4. Litigation
   a. Although generally a major trust eroding factor, litigation may still be a credible dispute resolution option if the dispute is one strictly of contractual interpretation or is mission critical to the economic interests of a particular licensing party. Often litigation is preferred by the licensing party with the deepest pockets for maximum procedural flexibility and protection. The advantages of litigation generally include the certainty of the decision, lack of necessary compromise, and the greater ability to forum shop, if and when required

B. Parties should also consider choice of law.

X. RISK ALLOCATION

A. Representations and Warranties
   1. In life sciences license agreements, representations and warranties are divided into two categories:
      a. First, the standard transactional reps such as a party’s due organization, authority to enter into the agreement and its binding nature, a party’s compliance with laws, third party consents, and litigation related to the licensed technology.
      b. Second, the reps more uniquely related to the intellectual property being licensed and the research and development. Examples of such representations and warranties include ownership of intellectual property (including references to specific patents and proprietary information relevant to the licensed technology, and, the prosecution and maintenance of specific intellectual property), status of specific research projects (including the conduct of such research in accordance with specific procedure and guidelines), and status of the development of other related or competitive products or improvements to the licensed technology.
      c. While the first category of reps is more typically included in license agreements, licensees should consider requesting the second category of representations and warranties specifically regarding the licensed intellectual property.
B. Covenants
1. Covenants are important provisions in most licenses, but especially in the case of more collaborative relationships where parties are relying on each other to provide certain information for regulatory purposes in order to obtain product registrations and protect product rights, or to develop or commercialize a product within certain established time frames or parameters.

2. Consider including covenants to develop a product through clinical trials and to spend resources to develop technology improvements.

C. Insurance
1. Consider requiring the parties to maintain in full force and effect certain types and amounts of insurance coverage covering general product liability claims and other potential claims related to activities to be carried out pursuant to the license agreement.
   a. It is not uncommon for each party to furnish to the other party certificates confirming the existence of the insurance required under the license, with information included on the deductible and/or self-insured retention and the effective expiration date of policies.

2. In certain cases, a party may want to be named as an additional insured, or loss payee, on applicable insurance policies.

3. Typically, insurance provisions will require a party to give a certain number of days advanced written notice of any cancellation, non-renewal or material changes in an insurance policy.

D. Indemnification & Hold Harmless Provisions
1. Parties should carefully consider the appropriate allocation of risk in drafting indemnification provisions. Typically, these provisions will include mutual indemnification obligations.

2. Define the limitations on indemnification:
   a. What and who is covered
   b. All costs incurred versus final judgment
   c. Process and procedures

E. Distinguishing indemnification and remedy provisions for product supply and manufacturing.
1. Parties should consider including different indemnification and remedy provisions to govern product supply and manufacturing versus technology licensing. Typically most supply agreements have limitations or caps on indemnification obligations of the supplier for breaches of the agreement, such as carve-outs for consequential damages and force majeure events or capped damage claims to the limits of applicable insurance coverage. Such limitations are not applicable in cases of gross negligence or willful recklessness. While such indemnification and limitation on damages provisions may be appropriate in the manufacturing and supply context, they are less common under the terms of the license itself as they relate to a breach of a representation or warranty related to a party’s knowledge of the intellectual property infringement of a technology, or its safety and efficacy.

F. Other Considerations

1. Damages / Limitation of Liability
2. Non-Competition / Non-Solicitation
3. Option / Right of First Refusal

XI. RULES & REGULATIONS AFFECTING LICENSE AGREEMENTS

A. Bayh-Dole Act

1. In the United States, much of the research performed at universities is funded, in part, by U.S. government agencies. The Bayh-Dole Act permits a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government.

2. Companies licensing in technology from universities, government or other non-profit institutions should keep in mind the government’s rights and down-stream requirements in any technology developed with government funding. If an organization elects to retain title to a subject invention for which it has obtained assignment, under the Bayh-Dole Act, the organization is obligated to do the following:

a. Grant to the government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced
for or on behalf of the United States the subject invention throughout the world;

b. File its initial patent application within one year after its election to retain title;

c. Notify the government if it will not continue prosecution of an application or will let a patent lapse;

d. Convey to the Federal agency, upon written request, title to any subject invention if the organization fails to file, does not continue a prosecution, or will allow a patent to lapse;

e. In each patent include a statement that identifies the contract under which the invention was made and notice of the government’s rights in the invention;

f. Report on the utilization of subject inventions;

g. Require in exclusive licenses to use or sell in the United States that products will be manufactured substantially in the United States; and

h. Agree to allow the government to “march in” and require licenses to be granted, or to grant licenses, in certain circumstances, such as if the organization has not taken effective steps to achieve practical application of the invention.

3. Certain additional requirements apply to nonprofit organizations:

a. Assign rights to a subject invention only to an organization having as a primary function the management of inventions, unless approved by the Federal agency;

b. Share royalties with the inventor;

c. Use the balance of royalties after expenses for scientific research or education; and

d. Make efforts to attract, and give preference to, small business licensees.

B. Export Controls

1. Export control regulations govern shipments of military items and less sensitive “dual use” biological material, including certain human, animal and plant pathogens, toxins, and genetically-modified organisms. The regulations also cover exports of
certain chemicals, materials (such as metals, graphite, and many others), and biomedical and chemical handling equipment (storage tanks, reactors, pumps, valves, etc.) sent abroad.

2. Certain scientific “know-how” requires an export license for shipment to non-U.S. locations or for releases to foreign persons, even if they are in the U.S.
   a. Know-how shared with certain foreign persons located in the U.S. (for example, employees, contractors, and visitors) may require an export license from responsible U.S. agencies.

3. To properly deal with export control regulations, companies must have a compliance program in place, and in particular, they must take a systematic approach to accurately classify their products and technologies under very specific regulatory classification lists.

C. Sunshine Act

1. The Physician Payments Sunshine Act (Sunshine Act) requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals. Manufacturers are required to collect and track payment, transfer and ownership information beginning Aug. 1, 2013. Manufacturers will submit the reports to the Centers for Medicare & Medicaid Services (CMS) on an annual basis. In addition, manufacturers and group purchasing organizations (GPOs) must report certain ownership interests held by physicians and their immediate family members.

D. HSR Act

1. Under a long-standing informal interpretation of the Premerger Notification Office (PNO) of the Federal Trade Commission (FTC), an exclusive IP license is viewed as a transfer of assets, and thus subject to the premerger reporting requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act). The HSR Act requires parties to reportable acquisitions of voting securities or assets to file with both the Antitrust Division of the Department of Justice (DOJ) and the FTC, and to observe certain waiting periods before consummating the proposed transaction.
E. Consider other rules and regulations that may affect the license agreement (for example, FDA and DEA regulations).

XII. REMEDIES FOR NON-DILIGENCE

A. Post-Termination Rights
   1. Determine in what situations licensee is permitted to sell off remaining inventory
   2. Determine sell-off period
   3. Describe policy and procedure regarding the return to licensor of materials used to manufacture product.

XIII. PUBLICATIONS / PUBLICITY

A. Generally, a university/institution wants control over use of its name, companies want to be able to tout the collaboration with institution, companies may not agree on the what could be said about the results of research this is especially true for clinical collaborations (e.g., did the study meet the primary vs. secondary end points?)

   1. Typically, universities and research institutions will want the right to publish articles based on the results/data from any research they conduct under the license agreement (in particular with respect to clinical trial results/data), to allow the Investigators full academic freedom (i.e. limiting the sponsor company’s ability to make any comments or edit publications).

B. Consider including provisions that allow for the parties to review and comment on any publications, as well as the right to redact any confidential or sensitive information that may be included in any such proposed publication.

XIV. TERM, TERMINATION, AND RENEWAL

A. Term
   1. Typically, the term of a license agreement will be based on the expiration of the licensed patent, or after a set period of time following the first commercial sale of a product.
   2. Determine life of the patent and/or patent application and set term accordingly

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B. Termination
   1. Define options to terminate the agreement prior to normal expiration (e.g., for licensee’s convenience, uncured material breach, patent challenge)
   2. Define flow of rights at termination/expiration, and other consequences.
      a. IP ownership and control may revert, or rights may remain (or be shared) with former licensee.
      b. Consider cross-licenses, if any have been granted.
      c. Consider joint inventions, if any were made through collaboration.
   3. Transition Planning
      a. Address timely, coordinated transfer of registrations and maintenance during the transition.
      b. Consider transfer of any ongoing development work.
      c. Consider supply terms, in particular whether they may continue or be amended to allow for additional supply during the transfer period.
      d. Consider support on safety reporting.

C. Renewal
   1. If appropriate, consider defining renewal options for the licensee.

XV. SURVIVING CLAUSES

A. Consider which clauses should survive in the event of the expiration of termination of the license agreement
   1. Confidentiality
   2. Publicity rights, publication, right to reference
   3. Indemnities
   4. Other Clauses
      a. In certain early termination scenarios, a party may want to retain certain license rights.
XVI. NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY

A. Background: In the summer of 2006, research officers, technology licensing directors, and other representatives from a group of top research universities, along with the Association of American Medical Colleges, gathered to discuss important societal, policy, legislative and other issues in university technology transfer. The result of the discussion was a white paper released on March 6, 2007 entitled, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” which identifies what they consider the most pressing of those issues. The paper is intended to guide universities in granting licenses to private parties for the rights to the universities’ intellectual property.

B. The Nine Points

1. Point 1: “Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so”
   a. Universities should clearly articulate the scope of reserved rights. In particular, universities should reserve rights to conduct research and permit other non-commercial entities to practice inventions and use associated information for research and educational purposes and to transfer tangible research materials and intangible materials to others in the non-profit and governmental sectors.

2. Point 2: “Exclusive licenses should be structured in a manner that encourages technology development and use”
   a. Universities should avoid overly broad exclusive rights agreements that stifle future research and development of the licensed technology. To facilitate this objective:
      i. exclusive licenses should include diligence obligations on the licensee;
      ii. licenses should not be broader than necessary to encourage development of the technology;
      iii. mandatory sublicensing or reservation of rights may be appropriate to meet unmet needs; and
      iv. in some cases (for instance, when licensing research tools) non-exclusive licensing may be preferable.
3. Point 3: “Strive to minimize the licensing of ‘future improvements’”
   a. Universities should seek to limit licensing of “improvements” or “follow-on” inventions in a narrowly defined way, including, for example, as to inventors, field, and duration.

4. Point 4: “Universities should anticipate and help to manage technology transfer related conflicts of interest”
   a. University technology transfer offices are well placed to spot potential conflicts of interest, for example in licensing intellectual property to a startup founded by faculty, students, or other university inventors. Universities should be mindful of such potential conflicts of interest.

5. Point 5: “Ensure broad access to research tools”
   a. Universities should consider a mixture of non-exclusive and field-exclusive licensing to ensure broad access to intellectual property comprising research tools.
   b. For example, if a university wishes to license a research tool to a company to optimize and sell licensed products and services for research, diagnostic or other end uses, the drafting of such an exclusive grant should make clear that the license is exclusive for the sale, but not use, of such products and services.

6. Point 6: “Enforcement action should be carefully considered”
   a. Litigation should be a last resort for resolving disputes, and nuisance suits should altogether be avoided. Where litigation is pursued, universities should keep in mind the primary mission of using patents to promote technology improvements for the benefit of society.

7. Point 7: “Be mindful of export regulations”
   a. Universities should be mindful of export laws and regulations, the detailed terms of which may affect the wording that should be used in know-how licenses in particular. Licensing “proprietary information” or “confidential information” can affect the “fundamental research exclusion” (enunciated by the various export regulations) enjoyed by most university research.
8. Point 8: “Be mindful of the implications of working with patent aggregators”
   
a. Patent aggregators typically work under one of two models: the “added value” model and the so-called “patent troll” model.
   
i. Under the “added value” model, the primary licensee assembles a portfolio of patents related to a particular technology, and are then able to offer secondary licensees a complete package that affords them the freedom to operate under patents offered from multiple sources. These types of patent aggregators may help facilitate successful development of new technologies by consolidating rights in patents that cover foundational technologies.
   
   ii. Under the “patent troll” model, the primary licensee acquires rights that cover a broad range of one or more fields with no real intention of commercializing the intellectual property.

9. Point 9: “Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world”
   
a. Universities should strive to construct licensing arrangements that ensure that underprivileged populations have low-cost or no-cost access to medical innovations.

C. Beyond the Nine Points
   
1. On November 9, 2009, a group of six top research universities, along with the Association of University Technology Managers (AUTM), released a public document entitled the “Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies,” which builds on the Nine Points, and provides a more concrete statement of goals as well as licensing practices to promote the availability of health-related technologies in developing countries for essential medical care.