Review of Key Clauses
in University/ Biotechnology Industry
Licensing Agreements

by

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ABSTRACT

Universities produce a large amount of inventions every year and are a useful source of intellectual property. More companies are realizing the importance of gaining access to this source of intellectual property through technology transfer.

To reduce any likely disputes stemming from poorly drafted technology transfer agreements between universities and the biotechnology industry, understanding licensing agreements that pertain to universities is critical. This paper reviews the mechanism of each key clause of a licensing agreement, the potential related disputes and how to avoid those disputes.

First, the Definition Clause deals with definitions of key terms in the agreement and becomes a basis for resolution when parties disagree. Second, the Grant Clause determines the kinds of rights given in the agreement - exclusive or non-exclusive rights, material subject to license, sublicensing/assignment of rights to third parties, and field of use. Third, the Best Efforts/Due Diligence Clause imposes the licensees’ obligation to commercialize the licensed technology. Fourth, the Royalty Clause is a highlight of the agreement and five different types of royalties will be covered – (1) upfront payments, (2) minimum annual royalties, (3) earned royalties (running royalties), (4) reach-through royalties, (5) patent cost, and (6) royalty-free licenses –. Fifth, most university agreements that cover patented technology contain a provision about infringement by others. This clause predicts how both parties will act if they have to bring an infringement action or defend one. Lastly, various other clauses such as Termination, Warranties and Indemnification, and Confidentiality will be covered. Warranties and Indemnification, and Confidentiality Clauses connected with a university’s publication policies may be peculiarly controversial in university licensing agreements because they often cover the conflicting policies between the industry and universities.

This paper presents a summary of the key clauses of a university’s licensing agreement and provides examples of possible disputes from each key clause. This review will be useful for negotiating and drafting a licensing agreement between a university and the biotechnology industry.
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I. INTRODUCTION

Universities historically pursued basic biological research with little or no effort to commercialize inventions, whereas the biotechnology industry developed products using mostly classical methods of chemistry and biology. The relationship between universities and the biotechnology industry was dynamically fostered by the advent of the Bayh-Dole Act of 1980, which encouraged universities to license inventions from federally funded research. Today, most research universities have their own office of technology licensing. In order to aid in commercialization of inventions that are owned by a university, many offices of technology licensing actively participate in a broad spectrum of industries ranging from large for-profit corporations to small, early stage firms. On average, American universities receive licensing royalties equivalent to approximately 3.4 percent of their research budgets. Especially, licensing of life science technology takes place frequently in university technology transfer. In 1998, 70 percent of all license income earned by universities came from the life sciences, with the remainder mainly from the physical sciences, including engineering.

If a university identifies a licensee (or a licensee identifies technology of interest at a university), the agreement is negotiated by the university’s office of technology licensing. Template license agreements are found at many university technology transfer offices’ web pages.

Many different provisions in a standard agreement are critical in speculating what kind of license the agreement is and what are potential conflicts. Unlike research contracts and grants, which tend to be specially tailored for universities, licenses often accept general licensing practices. By understanding the mechanism of general licensing agreements and recognizing potential issues specific to university licensing agreements, counsels for each side can appropriately assess and manage risk.

This paper will review key standard terms and conditions as well as special requirements for license agreements from universities to industry. Special emphasis will be given to technology transfer

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4 See, Everett M. Rogers, Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities, 12 AUTM 47, 50 (2000).


6 Note that reverse flow of licensing also exists, i.e. universities in-license technology. See, Yudhijit Bhattacharjee, Pitt Takes Over a Struggling Genetic Technology Firm, 303 SCIENCE 1449 (2004).
agreements between a university and biotechnology industry as a licensor and an original licensee, respectively within the United States.

II. KEY CLAUSES

A. Definition

When a dispute occurs, definition clauses play a critical role in determining a decision. Extensive definition sections are common in licensing agreements. Especially in a biotechnology licensing agreement, the definition clauses are often the longest sections of the agreement and highly technical in certain areas (for example, definitions including related but not identical to the principal molecule). It would be wise to write definitions that are easy enough for lay people to understand and clear enough to prevent any misunderstanding by the scientists who are actually involved in the licensed project. The definitions are also substantive. As a result, the definitions should be carefully drafted and reviewed. The following terms are selected definitions that are frequently controversial in licensing agreements.

1. Patents

Licensed patents mean U.S. Patent Applications, Serial Number xxx,xxx filed on xx/xx/xx and any divisions, continuations, continuations-in-part, reexaminations or reissues of any such patent applications or patents. For example, if the licensed technology is about a patented product, the licensee will have “the right to exclude others from making, using, or selling” the patented invention. Patents may include those filed outside the U.S. If a patent application has not been filed, the university may include a disclosure number and invention title with the inventors’ names.

2. Territory

“Territory” may mean the United States including its territories and possessions in a domestic license agreement, or all the countries of the world in a worldwide license agreement. However, if the license is solely patent rights, “territory” in a worldwide license would mean all the countries of the world in which licensed patents have already issued or will issue in the future during the term of the agreement.

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8 Id. at 47.
Furthermore, in considering how the licensed territory is defined, recent changes of trade barriers and economic spheres of the world should be given attention. For example, ten members will be newly added to the European Union (EU) in 2004. If company A has exclusive rights in Lithuania and company B has exclusive rights in the EU, who will have exclusive rights in Lithuania after expansion? The parties of an agreement may avoid such a problem by defining territory carefully.

3. Net Sales

The definition clause of “Net Sales,” if carefully defined, may prevent one of the potential disputes in licensing agreements. Its definition usually lists the items that would be deducted from gross sales of licensed products sold in the territory by the licensee. These items may include, (1) import, export, excise and sales taxes, and custom duties; (2) costs of insurance, packing, and transportation from the place of manufacture to the customer’s premises or point of installation; (3) costs of installation at the place of the use; and (4) credit for returns, allowances, or trades.

4. Improvements

Improvements to the licensed technology may be made either by the licensor or the licensee during the term of a license agreement. Improvements include modifications, enhancements or changes to the licensed technology. If the licensed technology is patented, the improvements that are specifically limited to modifications and do not change the identity of the invention would infringe one or more claims of the licensed patent. Minor improvements are often licensed to the licensee for little additional consideration. The licensor may require the licensee to grant rights in the improvements developed by the licensee through a grant-back provision. However, grant-back provisions should be carefully drafted so as not to violate anti-trust laws.

B. Grant Clause

Grant clauses in which licensors grant rights to licensees are the essence of the license agreement. For that reason, the granting clause obviously requires careful drafting. From both parties’ perspectives, the granting clause should fully and clearly set out the licensed rights. Grant clauses usually include (1) characteristics of a right (i.e., exclusive or non-exclusive, or option to acquire exclusive or non-exclusive

10 See infra pp. 16-17.
13 Id.
14 Id.
rights), (2) material to be granted, (3) a particular scope such as a specific field of use, a territory, or a certain amount of duration and (5) other rights\textsuperscript{15} such as sublicensing/assignment of rights to third parties.

1. Exclusive/Non-Exclusive Grant

An exclusive license allows only one company to license the invention with a higher royalty rate while a non-exclusive license allows more than one company to utilize the licensed technology with a lower royalty rate. In exclusive agreements, licensors including universities often want to reserve the right to perform more research in the license and possibly to sublicense the invention, whereas the licensee may not be able to assign or sublicense. Furthermore, exclusive licenses often include annual minimum royalties. Since the exclusivity or non-exclusivity of a grant clause in the agreement often determines the further necessary clauses, it is important to understand how it connects with other clauses.

Exclusive licensing is preferred when university-owned patents require significant private investment to reach the market place or are so embryonic that exclusivity is necessary to induce the investment needed to determine utility. In the pharmaceutical industry, drug development takes 10-15 years with an average cost of 800 million dollars\textsuperscript{16} until launching the products into the market. In such a case, the protection of exclusivity in the market would be incredibly important for any commercial licensee to successfully obtain a reasonable return on the investment of money and technical resources. As a corollary of this scenario, a licensor is faced with a potentially long period before there is any earned royalty and thus an extended period of good faith during the development and regulatory approval processes. The combination of long latency to pay-off and the strict necessity of exclusivity requires that both parties use good faith during the development and regulatory approval process. As a protection to universities in such a case, suitable provisions - such as upfront payments, milestone payments, requirement of best efforts, conversion of exclusive rights to non-exclusive rights, or termination - may be provided.

Especially in university technology transfer agreements, granting exclusive rights is problematic with respect to the federal tax exemption for universities. According to the Treasury regulations, “technologies developed by exempt institutions should be public goods made available to the public without restrictions on their consumption\textsuperscript{17}.” Therefore, a university that grants an exclusive licensing agreement cannot benefit from such a federal tax exemption and its income derived from such licenses

\textsuperscript{15} More often, the sublicensing or assignment rights are under a separate provision rather than under the grant clause.


\textsuperscript{17} Peter D. Blumberg, \textit{From “Publish or Perish” To “Profit or Perish”: Revenues from University Technology Transfer And the § 501 (c)(3) Tax Exemption}, 145 U. PA. L. REV. 89, 129 (1996).
should be recognized as private benefit –as if it were earned in a business distinct from the university’s educational and scientific exempt purposes - in terms of tax treatment under I.R.C. § 511\textsuperscript{18}.

Exclusive licensees often have little role in determining how to protect the licensed technology – for example, by prosecuting patent applications for the licensed technology. Some universities permit exclusive licensees to assume patent prosecution along with the costs. In such a case, the inventors would remain the same and the university is named as an assignee. However, this can become problematic when a licensee employee improves the technology and is added as an inventor\textsuperscript{19}.

On the other hand, the major factors favoring non-exclusive licenses are whether the patents are broad in scope and can be used in multiple industries. Non-exclusive licenses are preferred by universities when the technology can be used to foster development in many fields of use.

As a compromise, an exclusive, “field of use” license is a way to protect the company’s competitiveness while enabling the university to license more than one licensee, though in different fields of use. If a license agreement is defined by a specific field of use, the licensee would be given the right to enforce the licensed rights against third party infringers in the field of use to which the exclusivity applies.

**Right to Sue Patent Infringers**

An exclusive licensee who was transferred with “all the substantial rights” under the licensed patent can sue in its own name for infringement without joining the licensor\textsuperscript{20}. In *Vaupel Textilmaschinen KG*, the Federal Circuit held that the proper focus is on "the substance of what was granted." An agreement that transfers “all the substantial rights” conveys in full the right to exclude others from making, using and selling the patented invention in the exclusive territory, which is thus tantamount to assignment\textsuperscript{21}.

A non-exclusive licensee is not an “assignee” under the statute\textsuperscript{22} and has no standing to bring suit or even join a suit with the patentee because he or she suffered no legal injury from infringement\textsuperscript{23}. And a non-exclusive licensee of a patent has only a personal and not a property interest in the patent and this personal right cannot be assigned unless the patent owner authorizes the assignment or the license itself permits assignment\textsuperscript{24}.

\textsuperscript{18} Id.
\textsuperscript{19} Maxwell, *supra* note 4 at 520-521.
\textsuperscript{21} Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1380 (Fed. Cir. 2000).
\textsuperscript{22} See, *id.* at 1377.
\textsuperscript{24} Gilson v. Republic of Ir., 787 F.2d 655, 658 (D.C. Cir. 1986).
According to the Bayh-Dole Act, universities that created any invention under federal funding are required to reserve rights including a non-exclusive, non-transferable, irrevocable, paid-up right for the federal government. Under the federal government’s “march-in rights,” the federal government may require the university to license to a third party in certain circumstances.25

2. Option to Acquire an Exclusive/Non-Exclusive License

Some industries require the option to convert a non-exclusive to an exclusive license within a specified time frame. This may be useful where a company needs an exclusive license to cross-license.26

A licensor may preserve a right to convert an exclusive license to non-exclusive if the licensee has not commercialized a product within a certain period. From the industry’s point of view, this would be a potential disaster and thus great care must be used in drafting such a clause. For the drug discovery industry, gaining third party approval such as the Food and Drug Administration (FDA) before commercial sale should be counted as well in considering what would constitute a failure of commercialization within a period.

3. Material Subject to License

Licensable materials can be divided broadly into three categories; patents, know-how and hybrid of the first two. First, patents rights may include not only products, but also processes that are patented. If patent rights are licensed, the parties need to carefully define whether the rights are limited to specified, existing patents and technical information or are subject to expansion over time as new patents issue to the licensor and new technical information is developed.

Second, know-how licensing may include trade secrets, confidential information, or, more generally, information that can be considered a property right. For example, processes, procedures, protocols, and formulae may be know-how. For licensing purposes, know-how must meet the legal definition of a trade secret.27 Trade secrets must be preserved as secret by reasonable efforts. This conflicts with the university culture that favors publication of all research results. Another obstacle to protecting trade secrets in universities which are not business is the requirement that a trade secret be held by business. The Ohio State Court held that Ohio State University could have trade secrets.28

Furthermore, research done in universities despite its non-profit characteristics may be regarded as...
commercial activity because universities engage in their own business. Generally, information that a university owns in a patent application is recognized as a trade secret. Therefore, universities may own trade secrets and license secrets.

However, trade secrets that are not legally protectable may be in licensing agreements. In Warner-Lambert Pharm. Co., the plaintiff who paid royalties on the Listerine formula for 75 years still owed payment even though the licensed secret was known to public. The court held “

Third, university patent licenses frequently agree on a “hybrid license.” A hybrid license combines know-how rights with other property rights (i.e., patent rights). Frequently, the different expiration dates of those two rights cause problems. Patent rights have finite temporal limits; trade secrets do not. Therefore, if significant know-how is also licensed, the term could extend indefinitely. In such a case, the license fee should be adjusted downward, or renegotiated, after the expiration of the patents. Generally, the requirement of royalties after the expiration of patent rights is a patent misuse. In order to avoid this problem, the parties should specify separate royalties as to each know-how and other property rights (i.e., 75% for patent and 25% for know-how). Lastly, it is important to note that the know-how license may be nonexclusive even if the other property is licensed exclusively.

4. Licensed Field (Field of Use)

Frequently, the licensed technology can be applied to a number of fields. Licensed Field clauses restrict a licensees’ exploitation of the licensed technology. The limited field usually defines a particular field that the use of licensed technology is allowed, but it may constitute the style or class of the product made under the license agreement or the licensee’s right to sell the licensed subject matter for use only in certain defined fields. For example, if a drug candidate has multiple potential targets (e.g., multiple cancer targets, all requiring potential administration), there may be negotiations over the scope of the

29 See, Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002). The experimental use exemption to patent infringement was not available to major research universities “so long as the [research] is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. . . .”
30 Aston, Supra note 17 at 383.
32 Id. at 665.
33 Aston at 386.
34 Maxwell, supra note 4 at 539.
developments, the development priorities or sequence of development program. This negotiation may
devolve into an economic debate over the value of the drug candidate’s potential uses.

5. Sublicensing/Assignment

Sublicensing or assignment refers to granting all or a portion of an original licensee’s rights to
third parties. The default rule is, absent an express authorization by the original licensor, the licensee has
no sublicensing or assignment. However, it would be wise to express the right in the agreement to
avoid any uncertainty.

If the licensor and licensee have agreed that products based upon the licensed technology will be
marketed, manufactured or sold through third parties, sublicensing may be appropriate. If a right to
sublicense is granted in an agreement, it is desirable from the university’s point of view to describe the
right to collect royalties directly from sublicensees if the original licensee fails to perform.

On the other hand, since an assignment of a license constitutes a more fundamental change in the
original business relationship, anti-assignment clauses that limit the licensee’s right to assign make any
assignment of the contract void are common in license agreements. Indeed, a licensor will be reluctant
to agree in advance to substitute an unknown third party for the licensee. An exception to the non-
assignment provision is sometimes allowed in circumstances where the ownership of the licensee has
changed.

The modern approach to contracts in state courts rejects traditional common law restrictions on
the alienability of contract rights in favor of free assignability of contracts. In contrast, the Federal
Circuit Courts of Appeals held that patent licenses are personal and non-transferable in the absence of an
agreement authorizing assignment contrary to the state common law rule.

C. Best Efforts/ Due Diligence

A patent owner does not have any obligation to commercialize the technology, but university
licenses often require diligent commercialization of the licensed technology. The terms tie specific
timelines to certain milestones and vary depending on factors such as the type of licensed technology - i.e.,
drug discovery on average takes 10-15 years until approval by the FDA - and the stage of the technology
at the time of licensing. This clause is usually extensively negotiated.

35 Evans, supra note 11 at 17.
36 Id.
Best Efforts clauses are common in exclusive licenses and preferred by many licensors. Best
efforts impose to use the licensee’s “best efforts” to develop the invention to commercial utility or to use
“all reasonable efforts” to maximize the benefits to be realized by the licensor. In other words, the
licensee should perform its obligations with the effort that similarly situated companies would do from
their own research program. Best efforts clauses are prone to litigation and Courts tend to enforce them
in their literal meaning. Therefore, a better way to avoid a dispute is to set numerical goals with the
licensor. Absent any express provisions, it is unclear whether the licensee has an implied obligation to
the licensor. Courts may impose an implied obligation to use best efforts in an exclusive licensing
agreement.\footnote{See e.g., Permanence Corp. v. Kennametal, Inc., 908 F.2d 98, 100 (6th Cir. 1990); Emerson Radio Corp. v. Orion
Sales, Inc., 253 F.3d 159, 168 (3d Cir. 2001); Bailey v. Chattem, Inc., 684 F.2d 386, 397 (6th Cir. 1982). In Bailey,
the court held that the jury instruction to apply the implied standard of best efforts to commercialize the patent in the
exclusive contract was not erroneous.}

Due Diligence clauses impose the licensee to diligently proceed with the development,
manufacture, and sale or lease of the Licensed Product and diligently develop markets to meet certain
specified goals.

D. Royalty

The term “Royalty” is used to describe any consideration paid for the rights granted to the
licensee. Exclusive licenses typically require an up-front, non-refundable license fee which may cover
the costs of obtaining the patent, as well as running royalties and minimum annual royalty payments.
Non-exclusive licenses may have more flexible terms.

One of the difficult issues regarding royalties is the duration of royalty payments. If royalties for
patent rights are required beyond the term of the patent, it would constitute a patent misuse.\footnote{See,
Brulotte v. Thys Co., 379 U.S. 29, 33 (1964).} Thus, patent royalties may be paid no longer than the life of the patent. However, if a license agreement covers
multiple patent rights, a licensor would desire to be paid until the last of the licensed patents expires. A
solution is to have hybrid licenses by having different royalty rates apply to different kinds of patents and
having all royalty obligations expire when de facto exclusivity in the relevant territory ceases.\footnote{James S. Hilboldt, Jr., Technology Licensing and Litigation 1992, 334 PLI/PAT. 191, 198-199 (1992).} In such a
case, separate consideration should be made for each set of rights so as not to commit patent misuse.

This paper will focus on the following five kinds of royalty payments; (1) Upfront Payments, (2)
Minimum Annual Royalties, (3) Earned Royalties (Running Royalties), (4) Reach-Through Royalty, (5)
Patent Cost, and (6) Royalty-Free Licenses. In addition to the above kinds of payments, there are other
payments which are prevalent in university-industry licensing agreements such as Initial Payments and
Milestone Payments. Initial payments are generally coupled with periodic royalty payments. In
milestone payments, a university may also require certain "success milestones" coupled with a minimum amount of efforts to develop the technology, e.g., performing clinical trials by a certain date, getting the product on the market by a certain later date, etc. However, success milestones are particularly difficult to negotiate for technology in very early stages, where both the company and the university are conscious of many unpredictable technical hurdles in the product's development, making it difficult to demand specific dates for success.

1. Upfront Payments

This one-time fee at the execution of the license allows the licensor to recoup at least a part of the expense of developing the invention. Upfront payments are frequently required in know-how license agreements.

From the industry’s point of view, upfront payments are usually the least desirable because they represent the highest risk and most expensive type of payment in terms of the time discounted value of money\(^42\). However, in licensing proprietary reagents such as cell lines, antibodies, etc, upfront payments may be justified to be appropriate. As an example of an effort to dilute the impact of upfront payments, Stanford University, in support of their Cohen-Boyer patents licensing program, credited the upfront payments against future royalties\(^43\).

2. Minimum Annual Royalties

A minimum annual royalty provision ensures the licensor that the royalty will be no lower than a specified amount. This is especially prevalent in exclusive licensing agreements and protects a licensor’s interest in case the licensee is not diligent in developing or marketing a product based on the licensed technology. This provision may be set up to provide that if the royalty does not reach a set minimum amount after a certain period, (1) the licensor may either terminate the license agreement or convert the exclusive license agreement to a non-exclusive one, or (2) the licensee must pay the difference between the actual royalties paid and the minimum annual royalty amount.

3. Earned Royalties (Running Royalties)

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\(^{43}\) Id. at 120. Stanford University has come up with “a multiple credit scheme which gives to the licensee up to a five-fold credit for front end payments against royalties.”
First, a royalty comprising a fixed amount of money per unit of product sold is referred to as a “Fixed Unit Royalty.” This amount is easy to calculate and avoids disputes which may occur when accounting is based on profit.

Second, a “Sale-Based Royalty” is based on a percentage of the licensee’s sales of the licensed products. In the course of negotiation, parties may agree to use a percentage of the licensee’s gross sales as a basis for royalties. If the licensee’s net sales are used as a basis, the parties should negotiate and agree upon the definition of net sales. Accordingly, the license agreement should be clear as to the negotiated definition of net sales. For example, parties may agree so that the net sales price comprises the sales price after deduction of trade and quantity discounts, but before deductions of such other costs as freight and commissions. Three issues must be considered in defining the net sales price; (1) the items to be deducted from gross sales to calculate net sales; (2) agreement on how to apply the royalty to products that incorporate other technology in addition to the licensed technology (A clause as to net sales price of “combination products” is often added in the pharmaceutical setting); (3) the licensee’s accounting system suitable for calculating the negotiated net sales price.

Third, a “Profit-Based Royalty” is based on profits from the licensed product. A problem inherent in profit-based royalties is that companies have different means to calculate profits. Even in the same company, profits may be defined differently from year to year. Another problem is that licensees are usually reluctant to open their books to licensors. One way to alleviate the reluctance over disclosing financial material is for the license to provide for audits to be conducted by an independent party (e.g., an accounting firm). The auditor’s role would be limited to the accuracy of the reports stating details of the profit during a specific period and to records maintained regarding the manufacture, sale, use and other disposition of products sold or otherwise disposed of under the license.

4. Reach-Through Royalty

“Reach-Through Royalties” may be used. Recently, many universities developed research tools that can be used in developing a product, but are not themselves commercially viable products. Research tools comprise a broad category of materials or processes, i.e., cell lines or compound libraries that can be used for drug screening. In such cases, universities demand the payment of "reach-through" royalties based on the potential marketing of products. Reach-through royalties minimize or eliminate up-front

44 See, e.g. supra p. 4. A sample definition of net sales and an example list of the items to be deducted are shown.
45 Hilboldt, supra note 38 at 197.
46 See, Maxwell, supra note 4 at 529.
licensing costs and can be attractive to cash-starved companies that want innovative outsourcing arrangements. However, reach-through royalties have some problems. First, they have the effect of creating restricted access to subsequent tools and adding to the general proliferation of ties and competing interests that is the source of current access problems throughout the field. For this reason, the National Institutes of Health (NIH) disfavored reach-through royalties49. Second, by leaving open the time and the scope for calculating the value of a current use, they raise potential patent misuse problems both in terms of extending the time and expanding the scope of a patent grant; i.e., if reach-through royalties are required long after the patent on the research tool is expired. In contrast to NIH, a district court ruled that a license with reach-through royalties did not constitute a misuse on the grounds that the invention would be used during the term of the patent50. This notion is not consistent with the current design of the patent system because extending the valuation time violates the notion that patent holders have a limited time to capture a return on their inventions51.

5. Patent Cost

Usually, exclusive licensees agree to pay the university licensor for patent and related costs52. Universities typically will not patent inventions before soliciting industry interest. In such cases, the licensing agreement obligates the company to pay patenting costs and royalties in exchange for commercialization rights. However, some universities take an aggressive position with regard to filing for patents. For example, the Massachusetts Institute of Technology may file patents on any technology that has a reasonable chance of breaking even commercially53. In some cases, universities will allow a licensee to engage the licensee’s own patent counsel and file in the university’s name. In such a case, especially, if the license agreement is of the exclusive nature, the university may have attorney-client privilege with the company’s patent counsel regarding the common legal interest. In In re Regents of the Univ. of Cal., the University of California, after filing a patent application, entered into a license with an option to acquire exclusivity with Eli Lilly54. Eli Lilly’s in-house lawyers became responsible for prosecuting the foreign counterpart applications in collaboration with the University of California’s patent

52 Maxwell, supra note 4 at 519.
53 Kenneth Sutherlin Dueker, Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies, 52 FOOD DRUG L.J. 453, 502 (1997). “MIT takes a particularly aggressive position with regard to filing for patents. MIT does this to make the subject invention more attractive ex ante to potential licensees. . . . The majority of universities, however, do not have the resources to take such risks and will not patent before soliciting industry interest.”
54 See, In re Regents of the Univ. of Cal., 101 F.3d 1386, 1388-1389 (Fed. Cir. 1996).
The Federal Circuit held that the University of California had the requisite common interest with its licensee, Eli Lilly, such that the attorney-client privilege applied to communications between University of California and attorneys for Lilly.\(^\text{56}\)

Moreover, maintenance fees are also due in the U.S. at intervals of 3 ½, 7 ½ and 11 ½ years after the patent issues. Many universities seek to transfer the responsibility for such costs to the licensee, especially if the license is exclusive.

### 6. Royalty-Free License

Usually, a royalty-free license applies to (1) university licensing for internal, non-commercial research purposes to companies that sponsor research; (2) an antitrust case where a patentee is disproportionately powerful over the competitors; (3) a license to the government in return for research funding under the Federal Technology Transfer Act of 1986; (4) a cross-license between patentees in overlapping technology, neither of whom can develop products on their own; or (5) a license by a patentee employee to the employer over the invention the employee conceived during the course of employment.\(^\text{57}\) As in case (4) above, the problem can be solved by executing cross-licenses to each others’ patents. Commonly, companies agree to royalty-free cross-licenses, providing each party with the rights to manufacture and sell products without payments. However, cross-licensing may bring a serious antitrust issue when the specific cross-license amounts to an effort to exclude a specific competitor.\(^\text{58}\) Generally, a problem as in case (5) above does not occur because universities generally have patent policies requiring the assignment of patent applications to the university.\(^\text{59}\) In cases where faculty or students have challenged ownership by the university, the trend is in support of university claims that patent policies alone may be sufficient to require assignment.\(^\text{60}\)

### E. Infringement

The right to bring suit against infringers of the licensed patent rights is often heavily negotiated. The parties may add a provision regarding whether the licensor or the licensee or both in cooperation are

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\(^{55}\) Id.

\(^{56}\) Id. at 1390. The court accepted that the legal interest between the University of California and Eli Lilly was "substantially identical because of the potentially and ultimately exclusive nature of the University of California –Eli Lilly license agreement."

\(^{57}\) Maxwell, supra note 4 at 552-523.

\(^{58}\) Barton, note 10 at 349.

\(^{59}\) Id.

allowed to control the defense against infringement actions and prosecution against infringers. This provision may include the division of costs and any recoveries for the infringement.

On the other hand, the parties may be situated to defend suits against infringers brought by third parties. Where the licensor fails to defend the patent within the territories where the patents were issued, the licensee is entitled to have royalties reduced or eliminated. In university license agreements, if a university is a state university, the university may not be sued for patent infringement in a federal court unless it consents to the suit. In *Seminole Tribe*, the United States Supreme Court upheld a state’s immunity from patent suits. However the precise status of state immunity is unclear because the Federal Circuit Court limited the scope of the state immunity under abrogation theory and declaratory judgment suits under the implied theory.

Especially where a license is for core technology, the licensee will naturally want the rights to prosecute and maintain the relevant patents. Yet the licensor is unlikely to grant such rights if the license is nonexclusive or exclusive only for a limited field. At the very least, however, an exclusive licensee of a limited field should have the right to consult on the prosecution and maintenance of patent rights and to prosecute and maintain patent rights abandoned by the licensor.

Another important issue is that parties should take prompt actions. This becomes especially important in the pharmaceutical industry when a third party files an abbreviated application for new drug approval (ANDA) that is connected to the license in question. The Hatch-Waxman Act of 1984 allows generic drug companies to file an ANDA and the patent holder has forty-five days to file a patent infringement action, which would withhold FDA’s approval of the ANDA for thirty months. In such a case, the licensor and licensee must decide within forty-five days whether to bring an infringement suit against the third party.

Licensees may have enough economic incentive to challenge the validity of the licensor’s patent of the licensed technique. In *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the Supreme Court eliminated the licensee estoppel rule, which had precluded licensees from challenging the validity of a licensed patent.

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62 Kristen Healey, *Comment: The Scope of Eleventh Amendment Immunity from Suits Arising Under Patent Law after Seminole Tribe v. Florida*, 47 AM. U.L. REV. 1735, 1738 (1998). “First, a state may waive its immunity, either expressly or under the doctrine of implied waiver. . . . Second, Congress may abrogate state immunity to enforce the substantive guarantees of the Fourteenth Amendment, but only if its intent to abrogate immunity is made in "unmistakably clear language."”


However, the Lear abrogation of licensee estoppel does not apply if a license is entered into as a part of a settlement of a patent infringement lawsuit\footnote{Hemstreet v. Spiegel, Inc., 851 F.2d 348, 349 (Fed. Cir. 1988). The patent infringement defendant entered into a settlement agreement obligating it to make license payments regardless of whether the patents were subsequently held invalid or enforceable.}.

**F. Termination**

The default rule is that licensing agreements are terminable at will. However, licensors usually reserve the right to terminate the license agreement within a cure period in case the licensee (1) is in default of payment of royalty or providing reports, (2) is in breach of any provision thereof, or (3) provides any false report. In turn, licensees may terminate the agreement with written notice in a specific period in advance of the effectuation of the termination. A material breach of a licensing agreement gives rise to a right of rescission which allows the non-breaching party to terminate the agreement\footnote{Rano v. Sipa Press, Inc., 987 F.2d 580, 586 (9th Cir. 1993).}.

A licensee may wish to terminate the agreement because the development of a product using the licensed technology is unlikely to be successful, will be too costly, or because there is no longer great demand for the product due to changes in society. From a university’s point of view, adding a provision to allow the licensee to terminate with reasonable cause would be helpful to prevent any frivolous termination. However, the parties should be careful in determining what would constitute reasonable cause.

However from the industry’s point of view, the licensor’s sudden termination without cause may damage the licensee’s business plan drastically, especially when the licensee’s development of a product is near completion. Therefore, the parties should search for mutually acceptable mechanics for termination without cause.

The parties must carefully contemplate the results of the termination. After the agreement is terminated, the rights granted to the licensee revert back to the licensor and any further use of the licensed technology by the licensee would constitute infringement. The more contentious issue is about the licensee’s development and commercialization of the licensed technology. Parties should carefully draft the agreement to avoid such disputes.

Disputes occur most frequently when a licensee ends up in a bankruptcy proceeding. In the U.S., a provision that allows a licensor to terminate a license agreement upon the licensee’s bankruptcy is probably not enforceable under U.S. bankruptcy law. Since a bankrupt licensee is likely to breach contractual duties, such a provision is probably unnecessary. Bankruptcy proceedings often result in the termination of license agreements against the will of the licensees\footnote{Hilboldt, supra note 38 at 208.}.

\footnote{Hemstreet v. Spiegel, Inc., 851 F.2d 348, 349 (Fed. Cir. 1988). The patent infringement defendant entered into a settlement agreement obligating it to make license payments regardless of whether the patents were subsequently held invalid or enforceable.}
\footnote{Rano v. Sipa Press, Inc., 987 F.2d 580, 586 (9th Cir. 1993).}
\footnote{Hilboldt, supra note 38 at 208.}
Termination of an agreement, which is a premature cancellation, should be distinguished from its expiration (i.e., due to expiration of the licensed patent right). The consequence of termination of an agreement is that the licensee ceases to use the licensed technology whereas the licensee may continue to use it on expiration of the agreement.

G. Warranties and Indemnification

Reasonable warranties include that (1) the licensor has the necessary rights to grant licenses to the technology; (2) the issued patents are valid and enforceable; (3) the specified applications for the patents are reasonably likely to result in the issuance of patents that will be valid and enforceable; (4) the technical information disclosed to the licensee has been and will be accurate and complete. Universities, by nature, are not for-profit entities. Therefore, universities may not warrant the licensed technology, or the warranties would be watered down with the term “to the university’s best knowledge.”

Indemnification clauses are generally unlimited in scope and obligation to indemnify the licensor or licensee against any liability to third parties. From the industry’s point of view, it is wise to consider limiting the scope and obligation of indemnification. Especially in the pharmaceutical industry, it is typical that a licensor (a pharmaceutical company) will bear the responsibility for product liability claims and will indemnify the biotech company for losses. However, the issues of product liability in the pharmaceutical industry often relate to product development and labeling rather than the license itself. With divided responsibility, it may be difficult to allocate damages. In contrast, universities have little experience with product liability problems and tend to shy away from any responsibility because of the recognition of enormous judgments against defendants in such suits. The university may desire to be covered by a broad range of indemnification clauses. As a result, some universities have imposed onerous insurance and product liability requirements, especially if the licensed technology will be used in human devices or therapeutics. However, from the industry’s point of view, it is not reasonable for universities to escape from all of the responsibilities when they were the main party who developed the licensed technology and benefited from the commercialization of such technology. Industry may

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69 See, id.
70 Id. at 202.
71 See Abbott supra note 5 at 73.
72 Gould, Supra note 39 at 115. The author listed three reasons that may justify liability on the part of industry, but asserted that universities still have some responsibilities; “[e]ven though (i) the commercial partner will receive the major part of the revenues from the commercial activities, (ii) has the major input for product development during the transition from research finding to the commercial stage, and (iii) has the opportunity to review and test the technology developed by the University, it is still reasonable to expect that the University be responsible at least to some extent for injury resulting from its sole negligent acts.”
enforce universities to be responsible to some extent for injuries resulting from the university’s own negligence.

**H. Confidentiality**

Confidentiality clauses generally state which materials constitute confidential information. Information is excluded from confidential information if (1) the information was previously in the public domain, (2) the information becomes available to the public through no fault of the licensees, (3) the information is lawfully obtained by the licensees from a third party, (4) the information is independently developed by or for the licensees independent of any disclosure, or (5) the information is required by law or regulation to be disclosed.

Traditionally, confidentiality clauses were mainly for concerns of disclosure of confidential information to third parties or its misuse. Recently, not only the confidential information but also other information such as the agreement and its terms need to be kept confidential by both parties so that one party may have a maximum flexibility in negotiating with third parties. From the licensee’s perspective, the provision should not preclude the licensee from taking those actions that are necessary to develop and market the technology which may require revealing some or all of the confidential information.

Universities are generally more concerned with publishing their findings, while the industry is generally more concerned with maintaining confidentiality until their discovery is patented. Universities have policies that prevent them from agreeing to respective confidentiality provisions that would preclude publication of research and its results. For example, the policy of Harvard University includes a blanket prohibition against the performance of any research done on the University's time or utilizing its facilities that cannot be published, maintaining that such a restriction would be contrary to the mission of higher education. Generally, universities afford industry sufficient protection as to confidentiality of the patentable invention by granting disclosure rights to the opportunity to file patents. However, serious conflicts exist as to university-generated know-how or tangible results. In collaborating with universities, the industry is reasonably concerned that the university may prematurely release the corporately-funded invention into the public domain. Such release undermines patentability and the corporation's potential revenue stream.

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73 See, Hilboldt, *supra* note 38 at 213.
75 Gould, *supra* note 39 at 111.
76 *Id.*
As a result, publication provisions may be included in addition to confidentiality clauses. Publication provisions may contain approval rights of licensees with an opportunity to review and provide comments on all publication prior to submission. For example, agreements in state universities preserve the principal investigator’s absolute right to publish the results of his/her research. On the other hand, if industry was successful in gaining the general premise of some confidentiality of research information from a university, there are still problems as to how to bind a university’s staff with the agreement. The university may have to impose its employees who are involved in such a licensed project to sign employment agreements imposing confidentiality restrictions. Perhaps the major problem will be whether the university could enforce such agreements on its graduate school and whether the graduate students would be willing to participate in such a licensed project when there are restrictions on publications and disclosure.

Therefore, it will be wise for universities and industry to restrict confidentiality and publication rights as a compromise so that both parties may enjoy the benefits of the license to the full extent without imposing one side with losses.

III. CONCLUSION

In licensing agreements between a university and the biotechnology industry, it is very important that each party know the other and understand the possible conflicts that may arise. From the industry’s viewpoint, a company should be aware of the institutional policies and practices of the university.

When parties negotiate for a potential technology transfer agreement, attempts should be made to resolve all possible “what ifs.” During the negotiation, it would not be feasible to draft all possible contingencies into the agreement. Instead, if both parties agree to certain enunciated general principles of the deal in clear terms, this will allow the parties mutually acceptable flexibility to meet the unexpected circumstances which, more often than not, will arise during the lifetime of a license.

To facilitate a successful university-industry partnership, the following points are important: (1) Each right in the license and scope of the rights should be defined. Especially in a hybrid agreement, know-how should be specifically and carefully defined. (2) The royalty clauses should be stipulated so that it is clear how much value each right has relative to the whole royalty payments. For example, there would be a step-down in payments if only know-how is used. (3) Different expiration dates for the royalty provisions should be provided in order to avoid a patent misuse - one may not collect royalties after a patent has expired, even if the contract so provides. (4) Publication of the licensed technology, especially if the technology is know-how, will not itself terminate royalty obligations. Moreover,

77 Maxwell, supra note 4 at 571.
biotechnology is the most common subject in university licensing agreements. Given this fact, universities may want to collaborate with licensees in addition to licensing, which may bring more royalties to universities.

In conclusion, the genuine goal of both universities and the industry is to establish a “win-win” agreement, which means that neither party would maximize its rewards unfairly and to the detriment of the other party. Both parties should remember the partnership may bring rewards to both of them. On the other hand, if the licensed technology is not successful, the university should receive relatively small payments.\textsuperscript{78}

IV. SOURCE MATERIALS


\textsuperscript{78} Knox Bell, \textit{Win/Win Licensing: University to Biotechnology Company}, 22 BIOTECHNOLOGY L. REP. 9, 9 (2003).