§ 6A.01 Introduction

Biotechnology is a broad term that refers to the biological processes and recently developed technologies that utilize metabolic pathways and other capabilities of living organisms, or their component parts, for the benefit of science, commerce, and/or individuals. Though focusing on the manipulation of either the cells of multicellular organisms, or of single-celled microorganisms for some desired end, biotechnology encompasses such diverse disciplines as molecular genetics, molecular biology, immunology, microbiology, biochemistry, pharmacology, antibiotic production, fermentation technologies, and many others.

The laws of licensing patented technology have been applied to every conceivable type of business over many years. The application of these rules in biotechnology will be mostly the same, with some notable differences. Indeed, like any business, biotechnology will have some unique attributes of its own that will require application of the rules in ways different from other businesses.

This chapter will review the general laws of patent licensing with particular emphasis on the economic incentives and consequences that will affect biotechnology licensing. It will also review some of the key components of the biotechnology license, and will identify the issues that often arise during negotiation and enforcement of biotech patent license rights.
Finally, this chapter will provide an overview on patent due diligence as it applies to the biotechnology industry.

§ 6A.02 Objectives of a Biotechnology License Agreement

Biotechnology research is forever changing. Advances in genomics and gene expression have spawned many potential drug targets and compounds that may be applied to them. These new targets pose many financial challenges when large drug companies are unable to produce pipeline products in the biotechnology area. Such companies often look outside to supplement their portfolios. Biotech companies, particularly small, start-up companies, are fitting the bill, becoming the technology treasure troves of the industry. For this reason, among others, licensing is uniquely suited to facilitate biotechnology transfers from one entity to another.\(^4\)

The first step in preparing the biotechnology license agreement is to identify the objectives and reasons for entering into the license agreement. Such information will provide the blueprint for drafting the agreement, and will set the stage for the negotiations that follow. Without knowing how the deal benefits both parties, it is difficult to negotiate effectively.

There are numerous reasons why a biotech company may enter into a licensing agreement. For example, most biotech companies do not plan to use the technology itself. Instead, their only objective is to license the technology. Most often, the start-up biotech company has insufficient resources and/or expertise to exploit the technology in the market place. Therefore, most biotech companies pursue the path of licensing their technology to major pharmaceutical companies at the later stages of clinical development.

In some cases, however, the biotech company may desire only to exploit its technology in a particular geographic area or field of use. This may be done for various reasons. The biotech company may want to substantially increase the value and profile of its patent portfolio. In other cases, the biotech company may wish to license certain aspects of its technology as a means of generating income in the short term, or to fund long-term drug discovery in separate or related areas. Where appropriate, the biotech company may license its technology as means of building long-term relationships with major pharmaceutical companies, which could lead to other license agreements or joint ventures.

Likewise there are many reasons why it may be necessary for a biotech company to obtain a license to use technology owned by another. For example, obtaining a license enables a small business to expand its portfolio without the hazards and expenditures involved in an expensive R&D program.\(^5\) Also, it may become necessary to obtain a license to avoid an infringement action by a third party.\(^6\) Every biotech business should be cognizant of the necessity of searching for and avoiding infringement of third-party patents. In some instances, it may not be possible to work around a patent and negotiating a license is the only alternative to evade the time, expense and liabilities of an infringement claim.\(^7\)

Whatever the reason for entering into a licensing agreement, there are many important legal, business, and scientific considerations that must be taken into account before entering into the agreement. It is, therefore, important for both the licensor and licensee to identify and
carefully think through the reasons for entering the agreement, and then draft the license agreement with those reasons in mind. Consider the following scenarios:

1. When one party has expertise in the commercialization of technology and another party's expertise is in basic research, the license agreement should be drafted so that both parties can work together to their mutual benefit.

2. Licensees of biotechnology must be aware of the importance of having access to the second and third generation of the licensed products. Discoveries in biotechnology occur rapidly. Unless a licensee has access to improve products, the initial license is of minimal value. Therefore, it becomes necessary to create a license agreement that will foster an enduring relationship between the parties over a long period of time.

In short, understanding the reasons, benefits and goals (both long term and short term) of the license agreement to both parties is the first step in preparing the agreement. Only then can the parties effectively work out a mutually beneficial arrangement for both sides.

§ 6A.03 Key Sections in a Biotechnology License Agreement

As previously mentioned, all license agreements share many common elements. However, with respect to biotechnology licenses, special attention should be paid to certain aspects of the license due to the complexity of the technology and the nature of industry. Some of the key sections, which any biotechnology license should address, are discussed below.

[1] Background Section

Most licensing agreements have a "Background" section. This section generally sets forth the factual and legal predicates for the license. These may include: (i) effective date of the agreement; (ii) identification of the parties and; (iii) the parties motivations, skill set and expectations. An example of a typical "Background" section in a biotech license may appear as follows:

This agreement made effective as of August 1, 1980 by and between Company A and Company B.

Company A has expertise in the research, development and manufacture of genetically engineered enzymes, including bleaching enzymes.

Company B is a manufacturer of laundry products, which utilizes enzymes. Company B is also an expert in testing and evaluating enzymes for use in laundry products, and may be interested in utilizing bleaching enzymes in its products.
Company B desires to acquire from Company A the rights to use certain patented enzymes owned by Company A. Company A has agreed to grant Company B those rights as set forth in the agreement.

Company A and Company B are also interested in conducting research to jointly develop bleaching enzymes which are effective for use in laundry products and which are on commercial value of the Company A and Company B.

Some important considerations to keep in mind in preparing the "Background" section for a biotech licensing agreement:

-- Identify the expertise or business of each party. This information helps make clear the technological or financial contributions of each party to the transaction. This becomes especially important in joint development agreements.

-- Describe the parties' motivation and expectations in entering into the agreement. This information makes clear the contractual intent of the parties. Such intent may become critical in the event one party accuses the other of breaching the agreement. If the parties' motivations and expectations are set out in the agreement, then it becomes more difficult for one party to argue an intent contrary to that described in the agreement.12

-- When preparing the "Background" section, it should be drafted so that it clearly defines the consideration forming the agreement. This is particularly important in biotech licenses. For example, many biotech licenses involve products or process to be developed in the future by the licensor, or jointly by the licensor and licensee. In other situations, one party may have the option to exploit certain developments produced by the licensor. When the nature and source of the parties' obligations is based on the occurrence of one or more future events, the consideration between the parties may not be necessarily clear in the agreement. Such ambiguity could lead to future problems if one party seeks to excuse himself/herself from the obligations under the agreement on the grounds that consideration ceased to exist or has not been performed as promised.

[2] Definitions Section

Another important section of the biotechnology license is the "Definitions" section. Preparing this section may seem straightforward. It is not. Mistakes and problems frequently arise in drafting this section of a biotechnology license. For example, problems typically occur in defining the terms: 1) affiliates; 2) field of use; and 3) improvements, to name a few. The issues associated in defining these terms are discussed below.

[a] Affiliates

Defining the term "Affiliates" can be problematic. More often, corporate structure is extremely complex and fluid in the biotech industry. Small-start up companies are frequently
acquired or spun-off. Many such companies have key scientists whose involvement in product development is more valuable than any asset owned by the company. Therefore, much care should be taken in defining such terms as "parties" or "affiliates." For example, the licensor should make certain that the licensee's affiliates do not include the licensee's subsidiaries or other related companies that could sell the licensed product or technology to the licensor's customers.

Also, when defining the term "parties" or "affiliates," it may be appropriate to set out restrictions on the assignability of the licensed rights in the event one of the parties is acquired or merged with another, unrelated company. Consider, for example, Institute-Pasteur v. Cambridge Biotech Tech Corp., 13

Here, the debtor sought assumption of a patent license agreement and confirmation of a plan to transfer the debtor's stock to an entity that directly competed with the patent's licensor. The court found that the debtor corporation represented the same entity with which the licensor had originally contracted and, therefore, the debtor could not be prohibited from assuming the patent under Federal law. 14 Because the license agreement did not contain a "change in control" provision between The Institut Pasteur and Cambridge Biotech Corporation, the court found the transfer could not be prevented. 15

[b] Field of Use

Defining the "Field of Use" is equally important to both the licensor and licensee. For the licensor, it is important to define this term so that the licensor remains free to license related products or technologies to other licensees. The licensor, on the other hand, will want the broadest definition possible.

In the biotech and pharmaceutical area, it is recommended that fields of use be defined based on a particular medical condition. This is particularly appropriate for the licensor seeking to grant multiple exclusive licenses directed to different applications of the same technology. This approach minimizes the chance that exclusively licensed fields of use will overlap with each other, which could lead to problems for the licensor.

Consider the following hypothetical situation. The licensor licenses a broad patent on the administration of compound A in each of three fields: (1) increase production of lung surfactant in patients suffering from respiratory disease; (2) decrease production of glycoproteins in lung tissue; and (3) decrease production of carbohydrates in lung tissue. At the time, the licensor believed each field of use was distinct. Thereafter, it was discovered that compound A is effective in treating pediatric asthma because it increased the production of lung surfactant by preventing the overproduction of glycoprotein and carbohydrate in lung tissue. In these circumstances, it can be argued that each of the three exclusive licensees can make, use and administer compound A to treat pediatric asthma. However, by virtue of their exclusivity, they cannot. Here, the licensor is potentially liable for breach of contract. A licensor may, in some circumstances, avoid this particularly issue by defining the fields of use based on a specific medical condition.

c] Improvements
In most license agreements, the licensor retains ownership of the licensed rights. However, there is often a question of who has the right to use and exploit any future modifications made to the technology during the license term. Where rights in respect to improvement inventions are to be included in a biotechnology license agreement, there should be careful definition of the term “improvement.” Depending on the wishes of the parties, such definition may include, for example,

-- anything that performs the same function as the specifically licensed invention in a better or more economical way;

-- any beneficial modification of a component (or biological material) useful in the licensed invention; or

-- anything that performs functions similar to those of the licensed invention as described in a licensed patent and infringes the claims of the licensed patent.

It is highly desirable that the parties eliminate potential argument by providing a stipulative definition of their choosing. The following is a possible approach.

``Improvement, as used in this agreement, means any modification of a licensed product described in a licensed patent, provided such modifications, if unlicensed, would infringe one or more claims of the licensed patents."

Where the nature of the licensed subject matter leaves any room for doubt on the point, it may be prudent from the licensor's viewpoint to add an exclusionary clause such as the following. ``Improvement" does not mean or include developments to components, materials or processes useful in practicing the inventions of the licensed patents, but which do not themselves infringe the licensed claims of the licensed patent.”

[3] Obtaining Government Approval on a Licensed Product or Process

The biotech license agreement should clearly indicate the party bearing the responsibility for obtaining government approval for any product or process made, used, or sold under a license agreement. If the license agreement is silent on this issue, a court will probably impose the responsibility on the licensee, not the licensor, to obtain such government approval.16

§ 6A.04 Reach-Through Licensing

[1] In General

Much of the biotechnology industry is driven by basic research tools that efficiently generate vast amounts of data from life science research. Most often, these research tools represent a critical component to discovering potential blockbuster drugs. Rights to basic research tools can be obtained through licensing agreements. They can also be obtained through in-house development or through acquisition of a commercial venture. Of these, licensing
agreements provide the most efficient and cost effective means for acquiring access to current research tools.

The challenge in drafting a successful reach-through license involves identifying and resolving areas where the licensor and licensee have competing or conflicting objectives. The agreement should resolve these conflicts early, preferably during the negotiation phase of the agreement. Such conflicts may include cost issues, competition risks, and the exclusivity of the licensed research tool. Other considerations include governmental restraints, patent considerations and royalty arrangements.

The basic terms of a licensing agreement involving basic research tools does not vary much from a conventional patent license. For example, the provisions for the license grant, representations and warranties, acceptance and delivery, confidentiality limitations, termination rights are essentially the same as those found in conventional licensing agreements.

It is important to understand that the value of a patented research tool is not the cost that went into developing and patenting the technology. Rather, the value of the tool is based on those costs plus the value of the right to use the technology. Stated differently, much of the value is based on the extent to which the tool can further the licensee's research and development efforts. Such research could possible lead to a blockbuster drug that could generate billions of dollars in annual sales. Thus, one of the key issues in drafting a successful license involving research tools is compensation. In most cases, the value of a basic research tool is not known at the time of the license. Usually, the value is not known until an end product results from the research tool and the product has been approved for use in a particular country.

A somewhat controversial compensation method and/or royalty scheme available for patented research tools is "reach-through" licensing. "Reach-through licensing" is licensing of technology/intellectual property, typically patent rights, with royalties based on a percentage of sales, where the licensed technology, such as basic research, is not incorporated into the end product. In some instances, reach-through licenses are the only practical way to place a value on patented research tools, particularly when the value of it is not known or established at the time of the license. One commentator has noted that the royalties obtained from a reach-through license may not be that significant when compared with the return from the possible end product. In any event, parties are entering into reach-through licensing arrangements.


Some form of exclusivity to a basic research tool is vital to remain competitive. To acquire this exclusivity, companies must provide the owner of the tools a significant financial incentive to forgo profits otherwise available through multiple license agreements. In some instances, the financial incentive provided to some companies has been substantial. The costs for exclusivity may be reduced by limiting the licensor to a particular niche-market. This may require, the licensor to exclude specific companies from using the same tools and information to develop similar markets as those of the licensee. It has been reported that a large pharmaceutical company has entered into a large license agreement of this kind valued at $125 million dollars in 1995. Apparently, this agreement had been subsequently modified to permit companies in the niche-market that had been initially excluded in the original agreement.
When the niche-market approach to exclude specific companies is used, the licensor is taking a gamble that the research tool will produce a blockbuster drug. Thus, exclusivity provisions may create potential barriers to future royalties. For this reason a licensor should consider including narrowly defined niche markets by shortening the list of excluded companies to those of the licensee's direct competitors.

Exploitation of basic research tools by a licensee can theoretically generate a wide variety of third party claims against a licensor. These claims may include personal injury, death or property damage arising from the products produced or described by the licensed research tool. The licensor of a research tool should manage its risk of exposure to these and other claims by including an appropriate indemnification provision in the license agreement.

Generally, U.S. companies using biotechnology face no major antitrust problems. Nevertheless, there is some degree of uncertainty about the scope and applicability of the anti-trust laws to licensing agreements having niche-market exclusivity arrangements, such as those contained in a reach-through license.

In conclusion, there is much need to structure reach-through license agreements in ways that differ substantially from conventional licensing agreements, particularly in ways that provide the licensor and licensee flexibility on pricing, exclusivity and royalty terms. Reach-through license agreements involving basic research tools need to balance risks without burdening the agreement with unnecessary complexity. Effective agreements will contain carefully crafted provisions detailing the nature of the license, as well as addressing special concerns such as royalties, indemnification, and the proper allocation of risks and rewards.

§ 6A.05 Due Diligence As it Applies to a Biotechnology License Agreement

Intellectual property rights, particularly patents, are the core assets of most biotech companies. Ordinarily, patents form the center of any major commercial agreement with a biotech company. Before entering into any agreement involving intellectual property, particularly biotech patents, the party acquiring the intellectual property rights should conduct proper due diligence, especially patent due diligence.

Some of the more important areas of patent due diligence in the biotech area include: (1) ownership rights; (2) patent scope; (3) U.S. and foreign patent rights; and (4) existence of other agreements affecting the rights in the technology subject to the transactions. These particular areas are discussed elsewhere in this book, and these discussions are equable applicable to biotechnology license agreements.

The following represents a general outline of specific issues and activities unique to licensing agreements involving biotech companies and its patents.

Before acquiring a license to a particular biotechnology invention, the licensee should confirm that the license agreement includes all rights to the technology necessary to practice the patented invention subject to the license. This is particularly important in the biotech area due to the diverse nature of the technology. For example, consider a license to use a patented DNA fragment encoding a particular protein. It may be that the DNA is best expressed in genetically engineered cell line growing a specially prepared medium. The licensor has separate patents covering both the cell line and medium. Before entering into the license agreement, the licensee should be aware of these two patents and request that they be covered in the license agreement to use the DNA fragment.

To insure that the license agreement does not exclude critical technology, the licensee should review the licensor's entire patent portfolio relating to the subject technology. This includes both issued patents and pending patent applications inside and outside the U.S. Care should be taken to make certain that the scope of the patent search is sufficiently broad to encompass all relevant patents owned by the licensor. This will require searching the patent databases based on subject matter, inventor's name and the licensor's name, if different from the invention.

It will also require performing an assignment search at the U.S. Patent Office or other foreign patent offices.


In any patent due diligence, the licensor must take affirmative steps to confirm that technology subject to the license adequately covers the licensor's product or technology. This is particularly true for biotechnology patents. Indeed, the scope of these patents tend to be more narrow than they appear at first blush. It is important, therefore, that the licensee retain patent counsel to evaluate the scope of any patent subject to the license and make certain that it covers the product or technology subject to the license.


If a third party is involved in conducting research for the purposes of developing or improving the technology subject to the license, it is important that the licensee ascertain whether the third party is contractually obligated to assign all rights in the subject technology to the licensor. Often, a small biotech company employs university faculty members or graduate students to conduct research or provide consulting services. It is important that the licensee confirms that the relevant technology developed by these individuals will be owned by the licensor, and not the university under which the faculty member or graduate student is employed. The licensee's attorney should obtain all relevant consultant and employee agreements of the individual(s) involved in conducting research on the subject technology. These documents should provide information as to whether, and to what extent, the licensor will own the subject technology once developed or improved by the third party involved.
Third Party Patents and Technology

The biotech and pharmaceutical area is a very crowded art. Before entering into the licensee agreement, it is critical that the licensee conduct a search for patents that may be infringed by practicing the licensed technology. Also, due to the nature of technology and the money at stake (both in terms of investment and profit) the licensee should seek indemnity from the licensor in the event the licensee is charged with patent infringement by a third party.

Prior Art and Related Documents

As mentioned, the field of biotechnology is an extremely crowded art, both in terms of patents and published literature. Proper patent due diligence requires a prior art search to identify prior art that could affect the patentability, validity or enforceability of the technology subject to the license. Prior art searches are generally inexpensive and should be a major part of patent due diligence for a biotechnology license. Indeed, the identification of relevant prior art may cause the licensee to rethink its valuation of the license agreement or in severe cases to withdraw from the transaction. In some cases, the licensee could seek warranties from the licensor as to the validity or enforceability of the patent. In any case, the licensor is strongly advised to conduct a thorough investigation of the relevant facts before giving warranties.

Prior, Pending and Threatened Litigation

The potential value of patented biotechnology invention could exceed hundreds of millions of dollars in annual sales. While this windfall is great for the patentee, it could mean extensive liabilities and exorbitant litigation costs to any party accused of infringing the patent covering that technology. Indeed, any infringement action brought against a small start-up biotech company with limited financial resources could be disastrous for that company.

Thus, if the patented technology has been subjected to litigation, arbitration or any other legal proceeding, it is important for the licensee's attorney to confirm the status of those proceedings. This information may be obtained from the licensor directly, or through an independent search of the court's docketing systems. The copies of non-confidential documents filed in connection with a legal proceeding are publicly accessible. The licensee should obtain such documents to properly evaluate how a proceeding impacts his or her rights under the license or acquisition. Just as important, the licensee's attorney should ask to review any and all letters stating, implicitly or explicitly, that the patentee is infringing any third party rights. Failure to pursue such information may provide a basis for a finding of willful infringement by the licensee operating under the rights obtained in the transaction.

2 See id.


See id.

See id.

See Michelin, supra note 1.

See id.

See id.

See id.

See American Cyanamid Company v. Fermenta Animal Health Company, 54 F.3d 177, 182 (3rd Cir. 1995) ("Although extrinsic evidence may be considered under proper circumstances, the parties remain bound by the appropriate objective definition of the words they use to express their intent.").


Id.

But compare Syndia Corp. v. Lemelson Medical Education and Research Foundation, 165 F. Supp. 2d 128 (E.D. Ill. 2001). (Patent holder and related entities did not own or control technology patents that were subject of exclusive license, even though patent holder retained title to those patents and could withhold consent allowing exclusive licensee to initiate patent infringement litigation.).


See Id.


See e.g., Ligand, Inc. v. Pfizer, Inc., (Sup. Ct. California, San Diego County 1994) (Pfizer gave Ligand a lump sum and agreed to pay Ligand additional royalties based on the sales of compounds developed by Pfizer using Ligands research tool); see also Kowalski, supra note 3.

Restaino, supra note 3.

Id.

Id.

30 Kowalski, supra note 19.

31 See Restaino, supra note 1.

32 See Chapter § 2.12. see also Restaino, supra note 1.

33 Id.

34 See Commercial Biotechnology: An International Analysis, Chapter 18, p. 448.

35 Id. Compare Engel Industries, Inc. v. Lockformer Co., 96 F. 3d 1398 (Fed. Cir. 1996) (Court applied antitrust 'Rule of Reason' standard and held that royalties may be based on unpatented components); See also, Kowalski, supra note 3.

36 See Swycher et al, EFFECTIVE DUE DILIGENCE, Bio-Science Law Review (26 July 2001), available at http://pharmalicensing.com/features/disp/995877551_3b5beaf61e34. ("Due Diligence is a detailed investigation of the affairs of a business. The aim of due diligence is to identify problems within the business, particularly any issues which may give rise to unexpected liabilities in the future.").

37 See § 1.12, supra.

38 See § 2.12, supra for a detailed discussion on indemnification.

39 See Swycher et al., supra note 1.