

The American Bar Association  
Section of Science & Technology Law and the  
ABA Center for Continuing Legal Education  
Present

**Biotechnology and the Law:  
A Primer  
Parts One and Two**





**American Bar Association**  
**Center for Continuing Legal Education**  
321 North Clark Street, Suite 1900  
Chicago, IL 60610-4714  
[www.abanet.org/cle](http://www.abanet.org/cle)  
800.285.2221, select option 2

---



**DVDs, CDs, VIDEOTAPES, ONLINE COURSES, and COURSE MATERIALS**  
Interested in ABA-CLE self-study products? Visit the ABA Web Store at  
[www.abaclecatalog.org](http://www.abaclecatalog.org).

---

The materials contained herein represent the opinions of the authors and editors and should not be construed to be the action of the American Bar Association, the Section of Science & Technology Law, or the Center for Continuing Legal Education unless adopted pursuant to the bylaws of the Association.

Nothing contained in this book is to be considered as the rendering of legal advice for specific cases, and readers are responsible for obtaining such advice from their own legal counsel. This book and any forms and agreements herein are intended for educational and informational purposes only.

© 2007 American Bar Association. All rights reserved.

This publication accompanies the audio program entitled “Biotechnology and the Law: A Primer - Part One and Two,” broadcast on May 31 and June 7, 2007 (Event code, Part 1: CET7BLB; Part 2: CET7BLC).

## TABLE OF CONTENTS

### Chapter I

#### Start with the End in Mind

*Start-Up and In-Licensing Considerations*

Hugh B. Wellons, Esq.

### Chapter II

#### Feeding the Dream (or Beast!)

*Finance and Employment Considerations for a Biotech Company*

William N. Wofford, Esq.

### Chapter III

#### Playing Well With Others

*R&D Collaborations and Development Combinations*

Eileen Smith Ewing, Esq.

### Chapter IV

#### Staying Out of Jail, Win Park Place

*FDA Requirements, From Early R&D to Approval and Beyond*

Erika King Lietzan, Esq.

### Chapter V

#### It's Mine, All Mine?

*A Glimpse Into the Basics About Patents*

Dr. Christine C. Vito, Esq.

### Chapter VI

#### Hide and Seek

*General Litigation and ADR*

Robert F. Copple, Esq.

## LINK TO ADDITIONAL MATERIAL

### Chapter 1: "Introduction to Biotechnology and the Law" from *Biotechnology and the Law*

Robert F. Copple

<http://www.abanet.org/cle/programs/nosearch/materials/2007/t07blbcm2.pdf>

## **Discuss This Course Online**

Visit <http://www.abanet.org/cle/discuss> to access the discussion board for this program.

Discussion boards are organized by the date of the original program, which you can locate on the preceding page of these materials.

## **CHAPTER VI**

### **HIDE AND SEEK**

#### **GENERAL LITIGATION AND ADR**

*Robert F. Copple, Esq.*  
*Copple & Associates, P.C.*  
[www.copplelaw.com](http://www.copplelaw.com)

## **Introduction**

Whether the new biotech enterprise succeeds or fails, litigation will be an almost inevitable result. If the enterprise crashes, partners and investors will fight over the pieces. And shareholders will likely point at management's misdeeds as the cause of the demise. If, on the other hand, the enterprise is successful, creates intellectual property, markets a product, and makes a profit, it becomes a target for thieves, pretenders and, perhaps, some parties who have a legitimate complaint about the product or how the company is run. But such litigation is not always defensive. The enterprise may very well find itself in the position of the aggressor, protecting its assets or seeking to profit from its invention through licensing enforced by litigation.

The purpose of this presentation is not to turn business lawyers and in-house counsel into litigators. There will be no pithy and erudite discussions of the rules of civil procedure or evidence. Instead, this presentation has two goals: 1) On a topical level, identify a number of issues that are particularly applicable to the biotech enterprise that may give rise to litigation; and, 2) Discuss several techniques and processes that may help the business lawyer and her client to avoid or mitigate litigation and its effects.

### **I. PATENT LITIGATION\***

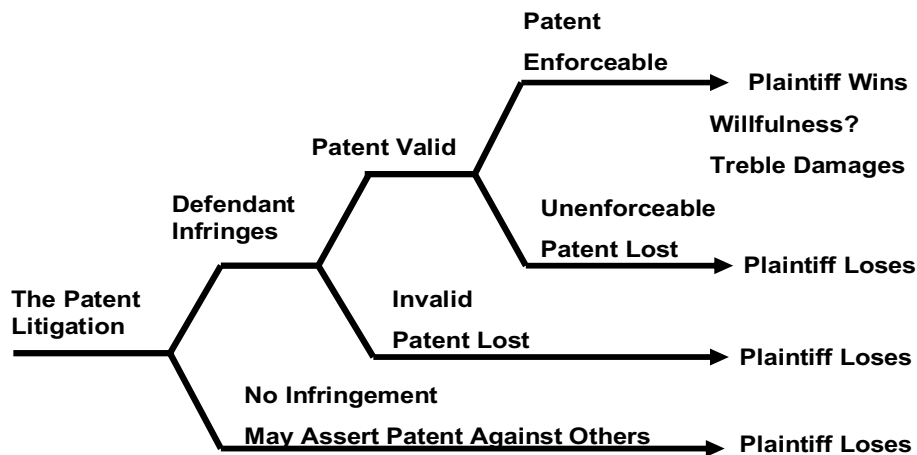
Intellectual property may very well be the most important asset, the crown jewels, of the biotechnology enterprise. Even so, the enterprise should not take patent litigation (either offensive or defensive) lightly. First, patent litigation is very costly, both in terms of the actual costs of litigation and in the impact on company resources, management attention, and investor perception. Although costs will vary depending on case size, company size, and the importance of the technology, one rough rule of thumb is to assign at least \$1 million of costs for each patent asserted in the litigation.

*\*In this discussion of patent litigation, I am indebted to Julie Fleming Brown who authored the Biotechnology Patent Litigation chapter of Biotechnology and the Law.*

- For example, if the plaintiff asserts three patents, the cost to each side may be \$3 million, or a total of \$6 million total. If the defendant counterclaims and asserts three of its patents back at the plaintiff, the cost will increase to \$6 million for each side or a total of \$12 million.
- In addition, patent litigation is not a zero sum game. Instead, it is more like the television show "Jeopardy" where the unsuccessful contestant can go into negative numbers. By asserting patents in a litigation, whether as plaintiff or defendant, the enterprise bears a real risk that the patents will be found to be invalid or unenforceable, which can result in extinguishment and complete loss of those patent rights.

### A) Patent Litigation at a Glance

Although patent law is a highly intricate area of jurisprudence with a heavy dose of science and engineering, in its simplest form, patent litigation can be reduced to three substantive elements – infringement, validity, and enforceability. If the business counselor remembers nothing else, he should remember these three elements and the impact of each on the patent rights at issue, as illustrated by the following decision tree.



### B) Strategic Considerations for the Biotechnology Lawyer

Counsel for the enterprise, whether defending a patent claim or seeking to enforce patent rights, must take a very thoughtful and strategic approach to any potential litigation.

#### 1) The Initial Demand and Opinion of Counsel

A demand letter directed to the enterprise alleging infringement should be taken seriously. Engage patent counsel to examine the patents at issue and the enterprise's product or invention.

Consider obtaining an Opinion of Counsel, which can later be used as proof of lack of willfulness to avoid treble damages.

#### 2) Choosing the Forum

**International Trade Commission.** Allows for a compressed litigation schedule and quicker decision. Damages not available, but if successful, may obtain an injunction prohibiting importation of the infringing product.

**Federal District Court.** Damages and injunction available. Depending on the jurisdiction, litigation may be protracted. If the plaintiff has not yet filed an action, the potential defendant may be able to pick the venue through a declaratory judgment action.

3) *Choosing and Managing the Litigation Team*

Patent litigation teams have a tendency to grow and expand. Manage the team and expenses by the “Swat Team” approach. Demand a small team of focused lawyers.

4) *Settlement Strategies*

Seek to optimize the result by developing dual track strategies involving both litigation and settlement opportunities. Work alternative dispute resolution into the strategy.

5) *Licensing Programs*

Licensing programs can be a good way to leverage technology and contribute to enterprise profits. However, such programs require very careful planning and execution regarding targets, royalty formulas, and protection of the asserted patents.

## II. OTHER BIOTECHNOLOGY LITIGATION ISSUES AND STRATEGIES

### A. Trademark

At some point in the successful biotech enterprise’s development, the company or product brand will be almost as important as its patented inventions. Essentially, the brand is to the business side of the enterprise what the invention is to the research and development side.

As defined by the Trademark Office, trademark protection can apply to “any word, name, symbol, or device, or any combination, used, or intended to be used, in commerce to identify and distinguish the goods of one manufacturer or seller from goods manufactured or sold by others, and to indicate the source of the goods. In short, a trademark is a brand name.”

1) *Trademark Litigation Issues – Infringement and Dilution*

**Infringement** occurs when a second party uses the same or similar mark for a product similar to that of the trademark holder in a manner that is likely to confuse the consumer as to the source of the product. In determining the likelihood of confusion, federal courts look to the following factors: 1) The strength of the trademark; 2) The degree of similarity between the two marks; 3) The geographic

and market proximity of the products; 4) The likelihood that the prior trademark owner may one day enter the market of the subsequent trademark holder; 5) Actual consumer confusion; 6) The defendant's bad faith in adopting the mark; 7) The quality of the defendant's product; and 8) The sophistication of the consumers.

**Dilution** of the mark occurs through blurring or tarnishment. At the outset, a claim for dilution requires that the trademark at issue be "famous." Dilution does not involve the crucial infringement element of consumer confusion. Instead, the injury caused by dilution is the undermining or diminishment of the trademark's distinctiveness. Blurring occurs when a registered and longstanding trademark is used by another party in conjunction with a dissimilar set of products. Tarnishment occurs when the trademark is used by the second party in conjunction with low quality or unseemly products.

2) Preventive Measures

- a) **The Trademark Audit.**
- b) **Trademark Registration**
- c) **Domain Name Registration**

B. Trade Secret Protection

The term of the legal protection for a trade secret is indefinite. And, the protection is effective for as long as the secret is properly protected or not otherwise independently discovered.

The Uniform Trade Secret Act defines a "trade secret" as:

information, including a formula, pattern, compilation, program device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

The goal is to develop and enforce a policy that demonstrates that the company has taken affirmative steps to protect its trade secrets. A confidentiality policy involving some or all of the following should be considered:

- 1) **Notice, guidelines, and non-disclosure agreements.**
- 2) **Noncompete agreements.**
- 3) **Confidentiality labeling and training.**



- 4) **Limit access.**
- 5) **Control or prevent copying.**
- 6) **Create general security measures.**
- 7) **Policy for departing employees.**

**The Inevitable Disclosure Doctrine.** An offshoot of trade secret law, the inevitable disclosure doctrine, has to do with the situation where an employee who has knowledge of a trade secret is hired by a competitor to perform the same or similar function. The concern is that the employee will not be able to separate her general technical skill, training, and experience from her knowledge of the trade secret and, eventually, will disclose the secret in the course of work for the new employer.

### C. **Products Liability**

A products liability threat to the new biotech enterprise must be taken very seriously, including the retention of experienced defense counsel. However, there are a few basics that the business lawyer should be aware of in order to help manage his client's risks.

Products liability is, for the most part, a creature of state common law and can reach any party in the chain from manufacturer to final retail seller, although manufacturers, including the innovating company, are the primary targets. A products liability action may be based on negligence, breach of expressed warranty, or strict liability. Over time, the historic differences between these doctrines have tended to blur. As a result, the key questions in virtually any products liability analysis are: 1) whether the product is defective in that it is unreasonably dangerous for its intended use; and 2) whether the plaintiff's injuries were caused by the product. Defects generally fall into the categories of design defects, manufacturing defects, and marketing defects. The scope of potential damages includes both compensatory and punitive damages.

Business lawyers can do a great service to their clients by recommending some or all of the following methods for establishing a record of compliance and responsibility:

- 1) At all points in the company's history, but particularly during the testing and trial phase of the biotech product, make sure the company is carefully complying with all agency protocols, regulations, and information reporting and sharing requirements.
- 2) Carefully and conservatively construct all warranties, disclaimers and public warnings in a manner to comply with law and agency regulations, and to be truthful in their content.

- 3) Assist your client in creating a document retention policy that complies with all agency requirements and centralizes document control.
- 4) Encourage the company to hold training seminars for employees regarding proper business use of voicemail, instant messaging, and email. Sensitive issues, accusations, rash comments, and loose talk should not occur in these media.
- 5) When the product has reached the marketplace, make sure your client keeps adequate records of consumer problems, complies with agency reporting regulations, and follows up on complaints as appropriate.
- 6) Encourage your client to make use of the attorney-client communications privilege and the work product doctrine.

#### **D. Document and Information Retention**

Given that document control, sharing, and preservation requirements of Sarbanes-Oxley, FDA regulations, and HIPAA, as well as concerns about discovery in potential products liability lawsuits and securities actions, is a very important issue for the new biotech enterprise. There are two other problems that further complicate any organized attempt at document retention. First, corporate document retention is not about saving every file, email, or scrap of paper. Instead, effective retention requires a plan or strategy to determine what information to save and what to discard. Second, for any new business that has been started in the last 10 years, it can be safely assumed that the vast majority of its records are stored in electronic, not hard copy, form. Electronic discovery can be debilitating expensive and may turn up difficult-to-explain documents or emails that the company had no obligation to save prior to the litigation. And once litigation is foreseeable, disposing of potentially relevant data can result in court ordered sanctions or even a default judgment.

With thought and planning, businesses can create electronic data life cycle policies that will eliminate potential liability associated with either saving too much or too little of the company's data; or more important, of losing control of what is there. An electronic data life cycle policy can be built around several basic principles.

- 1) Identify the objectives of the enterprise.**
- 2) Practice minimalism and save only what is necessary.**
- 3) Develop simple to implement policies and train your employees.**
- 4) Control distribution.**
- 5) Consistently practice and enforce policies and procedures.**

Information management is a dynamic concept that has changed, and will continue to change, in co-evolution with the gigantic "morph" of information from artifact to

ecosystem. Therefore, establishing data life cycle management policies is not a one time process. The advent of electronic data storage and digital communications has provided business, consumers, and the public with untold benefits, including access to vast amounts of information and incredible speed in analysis and distribution. Implementing and maintaining a data life cycle management system is a small, but necessary, price to pay for continuing to be a player in the marketplace.

## E. **Alternative Dispute Resolution**

Alternative dispute resolution (ADR) is the single best litigation management tool available to businesses. This tool can not only reduced the costs and business disruption caused by prolonged litigation, but also result in many early settlements that are substantially lower than would have been predicted under a more typical single track litigation scenario. Even so, many lawyers who are unfamiliar with these techniques reject ADR offhand as somehow a waste of time or a bad idea. The reality is that most commercial litigation is simply a cost of doing business. Like any business cost, the goal is to reduce that cost to an optimum level that achieves the business strategy without negatively implicating the company's health.

### 1) ADR Defined

ADR is really a group of techniques, all designed to assist warring parties in expediently and efficiently bringing disputes to an end. Most typically, ADR involves enlisting a neutral third party to help resolve the dispute through a narrowly tailored private mini-trial (arbitration) or through structured negotiations facilitated by an expert mediator (mediation).

#### a) Arbitration

Arbitration can best be described as a private mini-trial before a trained neutral who acts as a judge, reviews evidence, hears testimony, and makes a decision concerning who, if anyone, is at fault and the dollars, if any, one party may owe to the other for the damages. The key to arbitration is that the parties, not the courts, determine the scope and focus of the arbitration and what is to be decided. By agreement between the parties, the process can be tailored to best fit their needs and goals. If the parties can agree to narrow the arbitration's scope, as well as to limit the amount of discovery that has to be done before presenting the case to the arbitrator, an arbitration can be substantially cheaper than a trial to the court by 25 – 50%. And, arbitration can lead to a much quicker resolution of dispute, allowing the parties to put the matter behind them and focus on their core business objectives.

#### b) Mediation

Mediation is an entirely different process in which the parties retain a third party neutral whose job is to look for ways to move the parties towards an amicable settlement. A successful mediator brings to the table a variety of

psychological, business, and legal skills. The mediator's chief goal is to get the parties off their crystallized legal positions. In attempting to achieve settlement, the mediator will work to soften the individual parties' resolution by focusing on the weaknesses in their positions and the risks they may face by going to trial. Good mediators also employ creativity in looking for common interests between the parties that can displace the dispute, such as ongoing or future business relationships. Countless mediations have not only saved a strained business relationship between, say, a manufacturer and a supplier, but actually resulted in shared commitments to expand the volume of business conducted the parties.

## 2) *A Special Case for Patent Litigation*

The most difficult barrier to achieving resolution of a patent dispute in ADR is failing to fully understanding the financial complexity and competitive ramifications of a patent settlement or arbitration judgment. Most commercial litigation is resolved through the payment of a sum certain that is then incorporated into the balance sheets of the disputing companies and forgotten. It is more difficult, however, to quantify the value of a patent and its impact on future competition. That is, patent settlements and judgments often take the form of royalty fee per each use of the intellectual property. Past infringing use of intellectual property can be calculated with some degree of accuracy based on the number of units manufactured or sold. The uncertainty lies in attempting to estimate the number of times the intellectual property will be used in the future, i.e., a thousand product units or a million product units. In addition, the risk for the settling party having to pay the royalty may be whether its future use of the intellectual property will be in a low-priced product or a small part of a high-priced product. A fee per use royalty may cause a future low-price product to be too expensive to manufacture and sell. For example, the same semiconductor chip set or computer interface might be used in a low end computer peripheral or in a high end computer system. Likewise, ADR settlements may prove to be worthless where, as a result of changing technology and markets, what appeared to be very valuable results based on cross license, future royalties, or discount deals on products turns out to have no future value to the business. For example, at one time hard modem telephone intellectual property was extremely valuable. Now, however, with the advent of much more powerful computer microprocessors capable of performing "soft modem" tasks, hard modem intellectual property may be of little or no value.

The financial complexities are not an insurmountable barrier to resolution of such disputes. What is important is that counsel and senior management understand these complexities and integrate the corporate strategy people into the early stages of a patent dispute and resolution. To put it another way, the purchase or sale of a patent license, even as a result of ADR, is not totally dissimilar from the sale or acquisition of another business. Therefore, it is only natural that the strategy experts should be engaged to help quantify and bless any such decision. With this kind of upfront preparation, ADR can be successful in dramatically reducing the

transactional costs associated with patent dispute, as well as, often, leading to a more reasonable result between the parties.

It is important to remember that most patent cases do not stand alone. Instead, they are often part of ongoing licensing programs through which an inventor is systematically attempting to negotiate licenses with all of the manufacturers and users of the invention in a particular industry segment, i.e., all biotechnology manufacturers who use the same piece of equipment or make the same type of product. Successful licensing programs are built upon a series of licensing negotiations enforced by the threat of litigation. However, patent litigation also creates risk to the plaintiff who, in order to bring a suit, must put its IP on the line. That is, litigation of patent disputes is not a zero sum game that results in the plaintiff either getting a huge judgment or nothing. On the contrary, defendants will typically challenge the validity of the plaintiff's patents. If the patents are proven to be invalid as to that defendant, they are invalid as to the rest of the world, which means the end of the licensing program. Given these dangers, the plaintiff in a patent dispute could very well benefit from asserting a risky patent in a private arbitration where the result would be confidential, would not have binding precedential effect, and, by agreement, the decision of the arbitrator could be limited to a simple statement of win or lose without substantive explanation.

### 3) ADR Guidelines

Based on the above discussion, there are a few guidelines we can for effectively using ADR to reduce patent litigation costs and risks:

- a) At the inception of business relationships, try to lock ADR requirements into contracts with business partners who are in a position to potentially infringe your intellectual property.
- b) Every patent has two major components: liability and damages. Throughout the dispute process, give at least as much attention to the analysis of potential damages and business impact as you do to liability. The reality is that the liability issues are more subjective and the technical part of the team can argue about them all day. Damages, however, are what really count and are much more suitable for early evaluation and handicapping. Understanding the damages exposure will better enable you to weigh the alternatives and the potential use of ADR.
- c) At first notice of the dispute before litigation has commenced, take a hard look at exposure, impact, and costs, and consider the potential for an early mediation. ADR dispute research clearly confirms that the longer a dispute goes on, the more the parties' positions crystallize, and the more the damage claims escalate. Too often, counsel and clients do not take these initial notices seriously and miss the opportunity to resolve a dispute for a small fraction of what the claim will grow into by trial.

- d) Once litigation commences, it is important to develop parallel strategies. That is, treat every litigation as if you fully intend to go through trial. At the same time, it is important to step back and determine how you can direct and leverage the case into ADR .
- e) If the opposing side agrees to arbitration, take the time to create an agreement that limits the arbitration to only the issues that actually need to be decided, limits discovery to only what is necessary to try those issues, and carefully prescribes the arbitrator's authority and form of decision.
- f) If the parties agree to mediation, carefully select a negotiations team that has the expertise and authority necessary to resolve the case. Be ready to make a thoughtful and well-organized opening presentation of your best legal, technical, and business arguments. Although some neutrals will disagree about the value of opening presentations, the importance of such presentations is that often this is the first time the parties have heard the opposing positions other than through the filter of their own counsel. Then, at the right time, be ready to put the technical liability arguments to the side in order to try and come to a business resolution. Focus on resolution, not on who is right.
- g) Just because litigation has commenced does not mean that the parties cannot move the case to arbitration. Once the litigation issues have taken form, the parties may begin to see the risks of trial (i.e., loss of patents v. high damages award) and the advantages of a more limited private forum. Knowing this, focus your litigation strategy on heightening your opponents risk and leverage your opponent into arbitration.
- h) Finally, some parties, after spending millions of dollars on litigation costs, will then try to save a few bucks and choose their neutrals by price. This approach is simply foolish. The neutral fees will be insignificant compared to the litigation costs. Get the neutral who can best do the job.