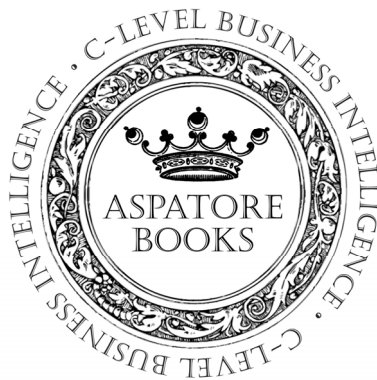


I N S I D E T H E M I N D S

Life Sciences Client Strategies

*Leading Lawyers on Intellectual Property
Management, Disputes, and Other
Key Business Considerations*



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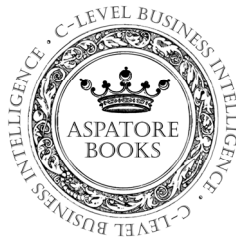
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Using Industry Knowledge and Experience to Advise Life Sciences Companies

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We counsel and assist life sciences companies in all aspects of their business and operations. Life sciences companies face all of the issues that confront other companies, such as financing, employment, governance, tax, facilities acquisition and operation, securities law compliance, and so on. In addition, life sciences companies face more specialized issues relating to specific forms of funding, building and maintaining strategic alliances, complying with government regulation, and developing, protecting, and commercializing intellectual property. Therefore, life sciences lawyers must have the resources to advise their clients with respect to both general corporate and commercial matters and the more specialized areas that are unique to clients in this industry.

Life sciences companies generally fall into one of two categories: large, established pharmaceutical companies, also known as “big pharma,” and smaller companies that own a technology or a platform of technologies from which they hope to develop a marketable product, which is normally a drug or medical device. For big pharma clients, we generally provide technical and legal advice regarding regulatory and intellectual property matters and help them negotiate agreements with manufacturers, suppliers, and smaller life sciences companies from which they seek to acquire additional products for their portfolios. Smaller companies range from start-up companies to public companies that have not yet marketed products or have only a limited number of products. For start-up companies—typically founded by a scientist or other person with high technical expertise but limited business expertise—we mentor and provide advice and education about all areas of their business. In doing so, we help them understand the environment in which life sciences companies operate, identify their needs, obtain financing, and structure and document their business relationships. As the start-up companies become more mature and their level of business experience increases, our focus often shifts to advising them about product development issues, technology transfers, strategic alliances, and public financings.

Main Areas of Life Sciences Law

The five specialized areas in which we most often counsel life sciences clients are: financing, primarily through venture capital and public offerings; protection of intellectual property; strategic alliances, including research

collaborations and co-development and co-marketing agreements; license and technology transfer agreements; and regulatory matters. There are unique processes involved in all of these areas, particularly in negotiating and crafting deals with venture capitalists, hedge funds, and other companies with strategic interests. Our experience with life sciences companies gives us insight into the wants and needs of both our clients and the parties with whom they contract, which allows us to provide special value to our clients by identifying issues of critical importance to them, conditioning their expectations, and helping them develop a realistic negotiating strategy.

In addition, there are other areas that may pose special challenges and opportunities to life sciences companies. For instance, there are numerous special commercial arrangements with terms and conditions unique to pharmaceutical and medical device companies that relate to (1) planning, conducting, and reporting of laboratory and animal research and human clinical trials, and (2) manufacture and supply of raw materials, packaging, and finished product. There are also areas of special legislation that provide opportunities for life sciences companies. One example is the Orphan Drug Act, which creates special incentives for development and marketing of drugs to treat diseases that are less prevalent than the large common diseases.

A special feature of the life sciences world is that contract research organizations, good manufacturing practice manufacturers, and others have formed a specialized satellite industry that works with life sciences companies. This makes it possible for emerging companies to increase the value of their businesses and to operate on a virtual, or almost virtual, basis by obtaining all or most of their operational functions from others. This covers everything from research and development to regulatory affairs, manufacturing, and even marketing, sales, and distribution. In connection with such virtual operations, it is important that life sciences companies have the benefit of counsel with experience in negotiating agreements with the participants in this satellite industry, since the life sciences company's prospects will be placed primarily in the hands of others.

For public life sciences companies, Securities and Exchange Commission reporting poses special issues related to the company's need to fulfill its

reporting and disclosure obligations without compromising its confidential intellectual property and strategic relationships or providing disclosure that is too optimistic. In addition, many emerging life sciences companies have to operate for many years before generating material revenue. Accordingly, they become “news-driven” businesses in that reporting of their interim research milestones and business relationships provides the only basis for investors and business partners to judge the status of their business. As life sciences lawyers in both of these contexts, we work with our clients and their public relations advisers to help them report both accurately and in a timely manner, based upon careful assessment and analysis of particular developments.

Helping the Client Finance Its Operations

Early- and development-stage life sciences companies generally obtain financing initially from angel investors and later from venture capital funds. For angel investor financings, we help our clients (i) prepare a business plan and related presentation materials for potential investors, (ii) determine a realistic valuation for the company, and (iii) structure the investment to meet the needs of the client and the investor consistent with customs and norms that have developed for early-stage life sciences investments. In connection with venture capital financings, we assist the client in the investor’s due diligence investigation and the negotiation of a term sheet, including the structure of the investment, and the transaction documents.

Ultimately, the successful start-up life sciences company either will go public or be sold. In connection with a life sciences company’s initial and subsequent public offerings, we act as the issuer’s counsel in connection with due diligence, negotiations with the underwriter, preparation of a registration statement to be filed with the Securities and Exchange Commission, and ongoing reporting. The financial markets have developed a number of specialized financial vehicles and techniques, such as PIPES and convertible debt, which have been very popular among public life sciences companies. We work closely with life sciences companies and their investment bankers to help evaluate the efficacy any particular financing mechanism in light of market conditions, timing, development timelines, company strategic plans, and related factors.

Helping Protect Intellectual Property and Obtain Technology Assets

Intellectual property is normally the basis of the business of a life sciences company, and therefore its protection is crucial. We first help our clients determine whether their intellectual property infringes on the rights of others. We then assist them in developing and implementing programs to maintain for themselves the exclusive use of their intellectual property. We help them determine whether their technology is patentable, what types of patents are available to them, the relative merits of such patents, and what the best patent strategy for them is. For technology that is not patentable, we help our clients determine what types of protection are available. These protections may include copyright registration and strategies designed to take advantage of common law protection for trade secrets. We also help them identify other ways of taking advantage of product exclusivity provisions under applicable laws dealing with new drugs and orphan drugs. Finally, we help them implement and enforce agreements with their employees and consultants, whereby the employees and consultants agree not to disclose or use the company's confidential information, except in connection with their work for the company, and to assign to the company any inventions they develop while working for the company.

Life sciences companies also often obtain or sell rights to technology. As described above, big pharma may want to obtain the right to market and sell a product developed by another company. Smaller life sciences companies may want to license their products or technology to big pharma for commercialization because they do not have the resources to develop a marketing and sales capacity. In addition, big pharma or smaller companies may want to acquire a particular piece of technology from another company to complement their own technologies. All of these transactions involve technology transfer agreements. We help our clients identify key issues, structure these relationships, and negotiate the terms of the arrangements. As part of structuring these relationships, we help our clients devise the best methods to divide property rights into separate component parts so different companies can pursue separate business goals without interfering with each other. Based upon our experience, we provide guidance with respect to creation and allotment of geographic, horizontal, and vertical markets, including restricted "fields" of application and related rules designed to maximize commercial benefits for the parties.

Special issues often arise in connection with licensing technology from colleges and universities or in international settings. In a university context, these issues commonly relate to insurance and indemnity, as well as balancing the academic need to publish and promote free exchanges of ideas against the commercial need to keep data and technology confidential. Based on our experience in the life sciences area, we are able to help our clients address these issues and develop arrangements that address the legitimate needs of all parties. There is also a special array of issues in international licensing related to matters such as (1) determining the countries and markets in which patent protection should be sought or maintained, (2) determining which countries impose special limitations or taxes on the import or export of technology or products, and (3) determining where, because of price controls, tariffs, or other reasons, it is best to have finished goods manufactured.

Helping the Client Develop Assets

Development of its assets by a life sciences company often involves complicated business arrangements. One way we can add direct value for our clients is by helping them form business relationships that maximize value to them. A good example is the strategic alliance often formed between big pharma, which is seeking additional products to sell, and a small company seeking financial and other assistance to develop and market a product. This can be a high-stakes relationship for both parties. For big pharma, it may determine the availability and economics of its products, and for the smaller company, it may determine whether it can develop and derive value from a product at all. These relationships raise issues regarding such matters as control of decision-making regarding development of the technology, rights to the technology, the duties and responsibilities of each party with respect to the collaboration, timing and amounts of payments, use and protection of intellectual property, exclusivity of marketing arrangements, and allocation of product liability risks. We help our clients understand these issues and identify their needs and goals with respect to the collaboration. Based on an analysis of the particular situation, we help our clients determine the appropriate legal structure for the transaction, which may involve licenses to make and sell products, co-promotion rights, distribution rights, or resale arrangements. We advise our clients about solutions to issues that will protect their legal rights and maximize value to

them while creating a viable working relationship with the strategic partner. In assisting our clients in forming these relationships, we focus on creation of appropriate business goals and incentives to maximize the chances that our client will realize the value it seeks from the relationship.

In developing and commercializing their assets, life sciences companies face a variety of regulatory schemes. Most importantly, the U.S. Food and Drug Administration regulates the development, manufacture, and marketing of drugs. A life sciences company that is seeking to develop a drug is subject to regulatory controls on pre-clinical and clinical testing. After approval of a drug, the life sciences company is subject to regulation affecting manufacture, labeling, supply, distribution, recordkeeping, reporting, sale, advertising, and marketing of its products. These regulations affect all areas of the company's operations. For example, in addition to advising clients about applications for approval of new drugs, we give advice regarding regulatory compliance for matters as mundane as construction contracts to build laboratories, animal facilities, and manufacturing plants. We help our clients understand and comply with these regulatory schemes and represent them before regulatory agencies. We also help them ensure that all their contractors and service providers are also aware of, and comply with, such schemes. We advise them on their reporting and interactions with the Food and Drug Administration and other agencies. Finally, we try to keep small problems from becoming large ones by counseling frequent candid interaction with the agencies via individuals and advisers who are expert on the matters being discussed.

Avoiding Danger: Common Client Mistakes

One mistake life sciences companies make is to give away too much to obtain financing. For the start-up and smaller company, financing is a critical and recurrent issue. These clients often believe they must let potential financing sources dictate all of the terms of an investment or strategic collaboration. While the provider of funding will often have significant leverage, the life sciences company may have more leverage than it realizes. In addition, there may be terms of a financing or strategic collaboration that are important to the life sciences company and less important to the other party. We help these clients identify their areas of leverage and the issues of greatest importance to them, and then help them

negotiate a transaction that will provide the necessary resources while minimizing any negative impact on the company's future.

We have seen a number of common mistakes made by small companies in doing product development or commercialization deals with big pharma. These include (1) giving big pharma overly expansive rights so it can in effect “shelve” or “back-burner” products or development programs key to small company growth; (2) assuming big pharma will assign the highest level of priority to business partnership activities, or that after a merger or consolidation such priority will not be reassessed; and (3) assuming customary financial incentives will motivate big pharma when competing strategic interests will normally prevail.

Another mistake we have seen with smaller life sciences companies that are developing drugs is a tendency to “bite off more than they can chew.” In an effort to maintain for themselves and their shareholders all of the economic value of a drug, these companies will attempt to take a drug through the clinical trial process at great expense when in fact a better strategy may be to enter into a strategic alliance with big pharma, pursuant to which big pharma shoulders some or all of the expense in exchange for some of the economic return from the drug. A related problem is the tendency of a smaller company to devote all of its resources to the development of a single product—also known as the “bet the ranch” strategy—when a better business plan may be to develop a technology platform that will support numerous potential drugs. This would ensure that the fate of the company does not rest on the successful development of only one product. While this type of mistake results primarily from business rather than legal considerations, we have found that experienced life sciences counsel can provide value to life sciences companies as they evaluate their strategies with respect to these issues.

Providing Value for the Client: Strategies and Approaches

We also provide value to our clients by advising them about the effects of applicable laws on their proposed conduct. Our goal is not only to advise the client about whether a proposed course of conduct is legal, but also, if it is not, to assist it in devising ways of meeting business goals that are consistent with law. Clearly, there is value to the client in being advised as

to what actions may run afoul of the law. Less obvious, however, is the value a life sciences lawyer can provide by suggesting alternative and legal ways of accomplishing the company's goals.

Similarly, we advise life sciences companies about the rights and obligations of the parties under their contracts. Since these contracts may govern matters that are key to the operations of the company (e.g., contracts that give big pharma the right to sell products developed by others or contracts that give smaller companies rights to require big pharma to finance product development), the company's failure to comply with these contracts or to enforce the rights they give it can have serious consequences. As life sciences lawyers, we help our clients understand their contractual rights and obligations and develop business strategies that maximize the benefits of those contracts to them.

In many instances, we have found that our clients have profited from following a course more conservative than that required or prescribed by legal or contract rights. For example, life sciences joint ventures depend not only on the quality of the technology, but also on the quality of the communications and trust between collaborating partners. We have often advised clients to communicate or perform more than a contract requires in the interest of building a positive and productive relationship.

To better assist our clients, we regularly keep a database of deals and deal terms negotiated by large companies, which we draw from Securities and Exchange Commission filings on EDGAR and from other publicly available sites. Whenever a client deals with a particular company that has a history, we research and know that history and, in effect, know in advance the kinds of terms and provisions we can expect from them. Because our knowledge of the life sciences field is valuable to our clients, we keep our own knowledge current by attending or participating in seminars and trade shows run by or for entrepreneurs and the members of the life sciences industry. Furthermore, we participate in industry groups that allow us to discuss and share experiences and insights as well as new developments in the law and the business environment. Finally, we participate in continuing education programs and read, on a regular basis, relevant publications, reports of cases, and other regulatory developments.

Client Strategies

Prior to the first meeting with a new client, we try to obtain as much information as possible about the client and the specific matter. For a publicly held client, this may mean reviewing the company's Securities and Exchange Commission filings and press releases, as well as any information the company has given us about the matter at issue. For a non-public company, it may mean searching the Web and asking the client to send us background information in advance. We also try to understand the technology, what the scientific community has to say about it, and what current and future development and operational milestones must be met for future success. If possible, we speak with scientists with whom we have a relationship for an independent assessment of the company's technology or story. Understanding the science leads to understanding the intellectual property, which leads to better assessment of technology transfer and license strategy and formulation of relevant business and legal terms with respect to such intellectual property, and it gives us a better understanding of the client's potential products, markets, and business needs.

In general, legal advice requires an understanding of the background and facts relevant to the matter. In addition, as described above, advice to a life sciences company is far more valuable when delivered in the context of the company's needs and goals. A complete understanding of the client's business and strategy is necessary for this purpose. We consider it a goal to provide legal advice that will advance the business of the client. In doing so, it is important to understand the short- and long-term business needs and goals in connection with product development and commercialization in order to help the client adopt a strategy, whether for seeking investment, business partnerships, or resolution of disputes.

Approaching a Dispute: Working toward Resolution

Our general approach is to resolve matters without litigation where at all possible. Litigation can be a losing strategy for a life sciences company even when it is nominally the winner. There are very few large pharmaceutical and medical device companies that are leaders in any particular therapeutic or diagnostic field and, accordingly, even the large companies may need to be able to form partnerships and other collaborative relationships. This can

be even more important for an emerging company looking for customers, distributors, and partners. In either case, the company needs to make as few enemies as possible and avoid a reputation as an entity that creates more problems than it solves.

Accordingly, we normally recommend multiple layers of dispute resolution for business collaboration and other agreements that make dispute resolution more likely than litigation and possible termination of an ongoing business relationship. In joint development agreements, for example, we have found that arbitration using “baseball rules”—in other words, where each side submits its best final proposal for resolution and the arbitrator must pick one—is often a good mechanism to keep people with disagreements talking when the stakes are very high.

As life sciences lawyers, we occasionally encounter a client who wishes to follow a strategy that is either unethical or runs afoul of the law. However, we have found that large businesses in this industry are normally populated by people who seek to act fairly and honorably within the bounds of their obligations, and we have consistently counseled that any bad or unethical behavior cannot only cause problems for a client in the matter at hand, but also ruin the ability to do business in the future. We remind clients that the Food and Drug Administration punishes “bad boys” on occasion in an official way, and the gossip network within the industry does so much more often in an informal way.

Formulating Client Dispute Resolution Strategy

In formulating a dispute resolution strategy for the client, it is critical to consider both the legal and non-legal ramifications of each course of action. To this end, we keep short- and long-term business goals in mind at each stage of the process. For example, an emerging company may be better served by accepting certain non-performance or underperformance from a big pharma development partner than by seeking legal remedies for damages or license termination and then having no big partner funding relationship at all.

When and if litigation becomes inevitable, we counsel the client to adopt a strategy and posture that is consistent with its long-term business goals and

to seek to avoid pyrrhic victories. Recently, we advised a client whose claims appeared to be “sure winners” to settle the matter in a fashion that achieved its primary business goals, while at the same time letting the defendants save face and achieve at least some of their goals. We have found that our life sciences companies generally understand these considerations and will work to settle the matter rather than litigate to the bitter end.

Obtaining Client Input

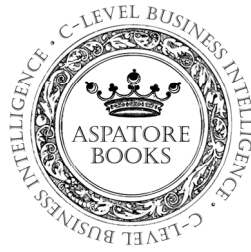
As in any litigation, it is important for a life sciences lawyer to gather and understand the facts behind the dispute. This means interviewing representatives of the client about the events giving rise to the dispute and reviewing any relevant documentation (e.g., contracts that are relevant to the dispute). If the dispute involves intellectual property, it will be important for counsel to have a full understanding of the technology at issue. This may require meetings with both the client’s technology experts and outside scientists. However, regardless of the nature of the dispute, it is critical for the life sciences lawyer to understand the impact of the dispute and its potential resolutions on the client’s short- and long-term business goals. Therefore, we work very closely with a client involved in a dispute to develop a strategy that both resolves the matter at hand and meets the client’s short- and long-term business purposes.

Final Advice

The biggest mistake we see lawyers make in this field is a simple lack of knowledge about the facts underlying the specific technology and market they seek to serve. Attorneys cannot advise and negotiate effectively if they do not anticipate the other side’s analysis of the financial and business value of a particular contract. If the attorney does not have the data and background about the client, the technology, the market, and so on that is available to the other side, he or she can only comment on legal concepts without knowing whether money and terms were left on the table. There are numerous publications, databases, and search methods available to allow one to know the market one negotiates in, and we counsel clients to allow us to employ them for their benefit.

Richard J. Pinto and Marsha E. Novick are business and finance lawyers and shareholders of Stevens & Lee PC, where he chairs, and she is a senior member of, its life sciences industry practice group. Based in Princeton, New Jersey, they have worked together for nearly twenty-five years, representing large and small companies in the pharmaceutical, medical device, diagnostic, biotechnology, and related industries in all phases of activity, including formation and governance, financing and securities law compliance, technology transfer, joint ventures, operations, and mergers and acquisitions. Both have played leading roles in numerous major finance and commercial transactions involving a number of leading public pharmaceutical companies, including some of the largest dollar-value strategic alliances in the biotechnology field. Mr. Pinto graduated from Yale University and the University of Virginia Law School, and Ms. Novick graduated from the University of Michigan and the University of Chicago Law School.

Dedication: *We wish to express special appreciation to the late Charles A. Faden, formerly president of Squibb Corporation and chairman and chief executive officer of Alteon Inc., for the education and friendship he provided in our working relationship over the years.*



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