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Risk taking: the key to securities law
By Regan Morris

Look no further than the complicated, costly process involved with developing a new drug, biologic, or medical device to understand why life science law practices are growing. According to a December 2004 Standard & Poor's Industry Survey on Biotechnology, creating a single new drug often requires researching and reviewing more than 10,000 substances. The report also estimated that on average, it takes 10-15 years to refine, test, develop, and shepherd that new drug through a labyrinthine regulatory process. And at what cost? Companies should plan on spending $897,000,000. That's right-897 million dollars.

What kinds of business organizations can best develop and market these new products and services? Where can they get the funding required to bring a new substance or device to market? Can or should they patent it? Would it be profitable to license the technology? What's the company's potential liability?

Perhaps legal conundrums like the preceding are in part why-when we asked several life science law practitioners whether they believed their area of the law was growing-their responses were unanimous.

"Definitely," commented Barbara Lano Rummels, Chair of the Life Sciences Group at Lindquist & Vennum. Ms. Rummels specializes in helping new and existing businesses raise capital through public and private financings.

"No doubt about it," commented William Janssen, Chair of the Life Sciences Practice at Saul Ewing, LLP. Mr. Janssen specializes in commercial and products liability litigation. "I think it's been growing for quite a while," agreed Areta Kupchyk, partner with Reed Smith and a member of its Life Sciences Division. Ms. Kupchyk specializes in FDA regulatory counseling.

"It has been a rapidly growing area of law," agreed Dr. William Noonan. "The high demand for scientifically trained patent practitioners has encouraged many scientists-and some physicians, such as myself-to leave their former careers to become patent attorneys."

What is Life Sciences Law?

A specialist in complex business transactions, a litigator, an FDA regulatory expert, and a physician/patent lawyer are four of the reasons Rummels is quick to clear up a potential misconception about life sciences law. "There is a life sciences industry," she explains. "Life sciences law is really more an industry focus than a particular area of practice." Rummels defines the life sciences industry as those businesses involved with medical devices, pharmaceuticals, biotechnology, or health care. It is an industry, she reiterates, "that encompasses a whole gamut of legal practice areas and expertise, including finance, intellectual property, and technology; regulatory compliance; and business counseling," to name only a few.

Janssen agrees with Rummels, but also takes pains to differentiate life sciences law from related practice areas, like medical malpractice.

"Medical malpractice law," he explains, "deals with the professional, evaluative decisions of whether to prescribe a particular product for a particular patient or to otherwise treat the patient in a particular way." In contrast, life sciences law, he feels, "offers a unique exposure to the intersection of legal and medical policy. It forces us to ask questions about strategic focus, national and international health directions, risk-and-benefit weighing, and the soundness of regulatory involvement in all of those processes."

A Changing, Growing Industry.

As the preceding indicates, the difficulty of coming up with a fixed definition of health sciences law is due to several factors. First and foremost is the dynamic nature of the technologies on which life science products and services are based. Perhaps just as important is the complex nature and legal needs of the business organizations created to develop and market these new products and services.

In April 2003 the Human Genome Project completed its decade-long effort, which culminated in the completion of the full human genome sequence. That Herculean task is just now resulting in the development of brand new treatments for a variety of human health problems and the adoption of new laws and legislation to regulate the development and application of those treatments.

Similarly, there was a time the demarcation between a pharmaceutical company and a biomedical devices company was clear and obvious. But in the last couple of years, companies have begun to develop hybrid products that

often blur the boundaries between drugs and devices. For more than a decade, heart stents have been used to clear out and reinforce critical clogged blood vessels. At first, those stents were simply biomedical devices. Today, companies are beginning to coat those stents with various types of drugs, increasing their efficacy. Should these new drug-coated stents be considered pharmaceuticals, medical devices, or some kind of new hybrid: pharmaceutically enhanced medical devices? And what types of legal and regulatory challenges do new hybrid technologies face?

Kupchyk specializes in FDA regulatory counseling and can attest to the complex process of shepherding any new drug or biologic through the FDA. Kupchyk believes technology is advancing so quickly that the lines between purely pharmaceutical or medical device companies is blurring. These newer companies, says Kupchyk, "are forging ahead with new ideas and approaches, and that requires and demands of us a new approach. I think that's why you see life science practice groups growing."

Does Practicing Life Sciences Law Require Any Special Expertise?

Given the complexity of the life sciences field, are there any special educational or experiential requirements for attorneys who might want to practice in the area? "It depends on the type of life sciences law you wish to practice," notes Janssen. "If your interest is in intellectual property [patent protection for new molecules, copyrighting or trademarking trade secret information, or advertising promotions], you may well find that a scientific, engineering, biology, or medical background is very helpful to you." On the other hand, if you're involved with raising capital or mergers and acquisitions, you may benefit from an M.B.A.

Before turning to private practice, Kupchyk worked for the FDA in the Chief

Counsel's office, where she was Associate Chief Counsel for Drugs and Biologics, in part handling drug and device litigation against companies who were in violation of the regulations. While Kupchyk does not have a medical or advanced science degree, she is quick to point out that it is sometimes extremely important and necessary to turn to IP lawyers on her own team who do have the necessary science background and expertise. But in the end, "the greatest service a lawyer can provide [health sciences] companies is helping them insure their information is translated for those who don't have degrees-to a courtroom, to investors, to jurors, and to the public."

Developing a Life Sciences Practice Area.

Given the cross-disciplinary nature of life sciences law, most law firms build their practices from within. "We looked at our collective experience," comments Lindquist & Vennum's Rummels, "and determined that we had the experience and skill to counsel life science companies at any stage in their development-from start-up to a mature business." Lindquist & Vennum's Life Sciences Group consists of approximately 30 attorneys, including lawyers with science degrees, intellectual property expertise, backgrounds in labor law, venture capital financing, mergers and acquisitions, health care, and regulatory experience. "We have the collective expertise," Rummels concludes, "to provide health science companies with the "whole package of what they need."

"Having attorneys who can provide that cross-disciplinary approach is really essential," agrees Kupchyk. "Today," she adds, "you have to have a 360 view of the world, and that requires a legal practice that can give you that view."

What are the downsides of a life sciences law practice? The practitioners with whom we talked had trouble conjuring any. Most of them agreed with Janssen,

when he characterized his practice as inviting "an ambitious lawyer into profound questions of legal and medical policy [that are] often envelope-expanding. At least from my perspective, it has been a thoroughly rewarding and fascinating area of practice. As soon as I discover the 'worst' thing about practicing in this area, I'll let you know."