
Biotech Law: A Profitable Practice Area Heats Up

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They toss around words like "recombinant DNA" and "genomics."

Many have masters', doctorate and even medical school diplomas hanging next to their law degrees.

They work on million -- and sometimes billion -- dollar deals that can lead to the discovery and production of new medicine.

They all have a love of science.

These are *attorneys*?

Indeed they are. And, in fact, they comprise a discrete but growing niche -- that of biotech law in Massachusetts.

David G. Conlin, a lawyer at Boston's Dike, Bronstein, Roberts & Cushman, explains that "a lot of people go out and get masters' and doctorate degrees, but after a while, it sinks in that their career will be focused on a very narrow [area of] work. Being a biotech lawyer is very exciting because we can work in all fields based on our technical backgrounds."

Conlin adds that the cutting-edge flavor of biotech law and the innovative

business strategies that each case involves are appealing to scientists-turned-lawyers. For example, a current "biotech battle" involves the scope of patent protection available for a protein worth billions of dollars used to treat anemia, renal disease and cancer. The ongoing U.S. District Court case pits Amgen, a California-based company that holds patents on the protein, against a Cambridge-based company called Transkaryotic Therapies, -- Inc. and its partner Aventis, which have discovered another way to make the protein.

A key issue is whether Amgen owns the protein or just one of the processes to make it.

Many biotech lawyers are watching the trial, as it could impact the level of protection available to other companies who hold similar patents and their exposure to competition.

And the more general issue regarding the scope of protection available to companies who discover potentially valuable biotechnology such as DNA sequences is also being debated.

"Is it fair to give someone protection for a genetic sequence that may be of limited utility now if that precludes research on it down the road by someone else?" asks Conlin.

Even though there are many uncertainties within this area of law, lawyers say that the biotech field is booming in Massachusetts.

Jeffrey M. Wiesen of Boston, chairman of the Biotech Group at Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, explains that "while Boston has always been a hotbed of biotech companies who find their routes in the

research universities and hospitals, the field has become hotter as the science has advanced to the point where companies have real products on the market and are making money."

Louis Myers of Boston, a senior biotech attorney at Fish & Richardson, notes that more and more scientists are responding to the market by seeking legal jobs.

"When I went to law school, I was seen as someone who was abandoning science and who was doing something greedy and pedestrian," he says.

However, pursuing a law degree today is an accepted career path for scientists and the only limit on the practice is finding enough qualified people to do the work, adds Myers.

Scientists-Turned-Lawyers

While not every biotech lawyer in Massachusetts can be called "doctor," a good number of them do have more than the average person's share of advanced degrees.

Alfred C. Server of Hale and Dorr's life sciences group, for example, not only went to college and medical school, but also earned a Ph.D. and did post-doctoral work prior to graduating from law school in 1994.

"I had a business, medical and science background and was told that the law was a very exciting field from the perspective of involving oneself in new bioscience technologies in ways that you couldn't necessarily do as a scientist," he explains.

But not all biotech lawyers have had such extensive schooling.

Edward R. Gates, managing partner and senior biotech attorney at Wolf, Greenfield & Sacks in Boston just had an undergraduate degree from Yale in biology and work experience in cancer research before he went to law school.

"I am one of the only ones left that doesn't have a Ph.D.," he jokes.

And while it may seem like large firms have the lock on biotech practices, Gates maintains that boutique firms were once the frontrunners in the field.

"We were the first here, but the large firms are now presenting extraordinary resources and competition to IP boutique firms who are starting to dry up from the pressure, particularly because of the salary raises we've seen recently," he says.

However, there are still a good number of those medium-sized firms around that are surviving the salary wars and competition for clients.

One way some firms are maintaining their talent pool is by hiring technical specialists and then paying for them to attend law school part time.

Gates notes that, at his firm, almost everyone hired after him has gone through such a program in the biotech group.

"These are people who come in with Ph.D.s and want to go to law school -- we even have two M.D.s so I don't have to leave work if I get sick," he says.

But even with these programs, most attorneys agree that it is difficult to find

enough lawyers with the appropriate backgrounds.

"A lot of Ph.D.s are technically brilliant, but they also must have the ability to become good advocates," says Conlin.

Uncertain Rules

The type of work that biotech lawyers do seems to be as varied as the diplomas on their walls.

Generally, there are at least four main areas within the field: patent prosecution, licensing, litigation and business counseling.

A central theme in many of these fields, particularly patent law, is that the products often are made from or involve recombinant DNA technology or genetic engineering, according to Myers.

"The products range from actual medicines given to people to new research tools used by people in the biotech industry," he explains.

Myers, who is a lawyer/Ph.D., adds that Massachusetts is one of the best places in the country for biotech law because there is so much activity here.

"The clients tend to be pretty sophisticated. They have been in the business for a while and are doing exciting things both scientifically and businesswise so you get to be involved in very cutting-edge science and in novel business strategies," he says.

Server points to deals his firm has worked on as examples of such exciting projects.

For instance, the Hale and Dorr life sciences group participated in the \$465 million pact between Millennium Pharmaceuticals and Bayer AG, which was believed to be the largest drug-discovery deal in biotech history.

Server adds that his group also worked on the establishment of a consortium of pharmaceutical companies, which was made up of 10 of the world's leading pharmaceutical companies and the Wellcome Trust of London.

"Their goal was to support academic institutions in their effort to generate information on the subtle differences between groups of individuals in the human genome," he says.

Server explains that if small companies were to obtain patent protection for this body of knowledge, they could block pharmaceutical companies from exploiting that knowledge.

"But if the information was released to the public, then all companies would start on common ground -- and that maximizes the chances that there would be productive output," he says.

Server notes that his group prepared documents that led to the formation of the consortium in 1999, as well as agreements forming a patenting strategy that would allow the property to be protected until the point at which it was released to the public.

Wiesen adds that a unique feature of biotech deals is that they tend to run on a much longer time-frame than typical corporate deals.

"You often have to think in five-to-10 year timelines before you know if you have a successful collaboration," he says, noting that it is important to set up

provisions in agreements that do not make success contingent on any one person's involvement, as the people who start out negotiating the deal likely will have moved on by the time the deal reaches fruition.

And uncertainties in the law also provide a unique aspect to these cases, according to attorneys.

"It isn't entirely clear how the Food and Drug Administration will deal with some of these new drugs or how much IP protection will be provided to clients," says Server.

He notes that it is challenging to create deals with the maximum amount of protections without knowing how the patent laws will change or how the FDA will treat certain products.

"These are not cookie-cutter deals, so we have to build in a range of protection for various scenarios," says Server.

Cutting-Edge Issues

As the law develops in this area, biotech lawyers note that there are many important legal issues they will be dealing with in the years ahead.

For example, the question of genetic privacy will be a hot topic of debate, according to Wiesen.

He explains that while most people won't want it known that they have a gene that predisposes them to a certain disease out of fear of discrimination by employers or insurance companies, researchers would benefit from such information in the course of developing drugs.

"The challenge is to protect people's rights to privacy in a way that doesn't stifle genetic research," says Wiesen.

While it sounds easy to write laws providing such a balance, it is, in actuality, very difficult, according to Wiesen.

"Every time you write down 10 words to make rules, five people will have a slightly different interpretation of what those words mean. Biotech lawyers are very involved in working out such language," he says.

Wiesen notes that, eventually, the courts will have to become involved with the interpretation of such laws and rules.

He adds that another unresolved issue is whether there will be increased government intrusion in drug pricing and how that will affect the sharing of proceeds between parties.

And the degree to which genetic information can be patented is also uncertain.

According to Conlin, the federal circuits have been narrowing the kinds of protections available to correspond with what was actually done to file the application.

"For example, partial DNA sequences are something that may turn out to be useful and a lot of them are being generated in the Human Genome Project, but the ultimate uses of DNA sequences are probably not known by the people who discovered them," he says.

So the U.S. Patent Office and the courts are struggling with how much protection should be issued, as there is a concern that someone might patent a sequence of limited use right now, thus preventing someone down the road from using that sequence in their research, notes Conlin.

"At this point, the Patent Office is trying to deal with it by issuing rules and guidelines as to what kind of disclosure has to be given, but there may be legislation in the future," he says.

These are the compelling issues that keep biotech lawyers in the law and out of the lab.

"A new product or method is inherently cutting-edge and it provides such a diverse workload so that every hour of the day you can be doing something different," says Cara Z. Lowen of Dike Bronstein in Boston.

Wiesen agrees that biotech law is an excellent niche to be in because it provides a high level of job satisfaction.

"I feel like I have made contributions to the development of a number of drugs in the market that save lives because I put together the deals that made them possible," he observes.-

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Page: 28 M.L.W. 2213