Biotechnology Becomes a Hot Commodity in Law Firm Practices

[by Danielle Cohen]

As the biotechnology field continues to grow--from the creation of genetically engineered foods to the mapping of the human genome--so, too, does the law field representing it.

Law firms are developing and expanding their biotechnology practices, bulking up their staffs with lawyers experienced in patent, intellectual property, and regulatory practice areas, as well as those with knowledge in science and research.

In October, Winstead, Sechrest & Minick P.C. launched a full-service biotechnology practice at its firm in The Woodlands, TX. About 25 of the firm's 320 lawyers work on biotech cases.

"We see a real opportunity out there in biotechnology," said Jeff Harder, head of the firm's biotechnology practice. "This was kind of a hot topic in 1985 as being 'the next great thing,' and here it is almost 2005 and it still is a hot topic and still 'the next big thing.' That's the staying power and potential of biotechnology."

Biotechnology is to law firms today what the hi-tech industry was to law firms in the 1990s with the explosion of practices focusing on Internet- and telecommunications-related needs.

According to the Biotechnology Industry Organization, based in Washington, DC, the world's largest biotechnology association and advocacy group, there are more than 1,400 biotechnology companies in this country.

Among the hot-topic legal issues in biotechnology practices are the creation and regulation of genetically engineered food and drugs, investor/shareholder lawsuits, and the control of intellectual property through patents.

"Intellectual property is absolutely the most important issue for biotechnology companies, along with efficacy and safety," said Mr. Harder, who specializes in corporate securities transactions.

Mr. Harder recently closed a $37-million-investment deal for the biopharmaceutical company Rejuvenon Corp., which has since started clinical trials for two drug candidates that could combat weight loss associated with cancer.

This past summer, Mr. Harder also worked on a transaction for the Galveston biopharmaceutical company Chrysalis BioTechnology Inc., in which the company was bought for $37.5 million by OrthoLogic Corp. and went public.

Numerous major lawsuits have popped up within the biotech industry over the past few years.

In 2000, U.S. farmers filed a class-action lawsuit against the makers of StarLink, a bio-engineered corn that accidentally entered the food supply, alleging StarLink hurt their business. The case was eventually settled for $112.2 million.

In 2002, the biotech firm ImClone Systems Inc. was involved in a high-profile case when its former chief executive, Sam Waksal, was convicted for insider trading after ImClone's experimental cancer drug, Erbitux, initially did not receive its widely expected FDA approval.

Michael Gaba, a partner at Holland Knight LLP, said the legal field is "playing catch up" to a biotech industry that keeps "pushing the envelope."

"As far as legal issues a company has in dealing with a breakthrough technology, they clearly have issues related to intellectual property," Mr. Gaba said. "The complexity of the technology relates to the complexity of the legal issues."

Mr. Gaba co-chairs Holland & Knight's 75-member Health Law team and the 25-member Food and Drug team at its Washington,DC, office, which provides a full range of services to biotechnology, pharmaceutical and medical-device clients, including corporate finance and structuring, intellectual property litigation and regulatory components at the federal level and in several states.

The firm, which works with approximately a dozen biotech-related clients at a time, has had its health team for many years but started its food and drug team about a year ago.

Mr. Gaba, who specializes in legislative and litigating healthcare practices, has worked with many clients on "combination products, such as medical devices that are part device and part biotechnology," including a device with human skin cells that can aid a diabetic with a foot ulcer generate new skin and a

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surgical patch that includes bovine pericardium to help heal wounds.

Perhaps the biggest day in science recently was the announcement in 2000 that scientists had mapped the human gene. In the years since, numerous requests have come from various companies seeking patents related to the project from the U.S. Patent and Trademark Office.

Dale Rieger, a principal with Fish & Richardson P.C.'s San Diego office, specializes in U.S. and foreign biotech and pharmaceutical patent prosecution. Biotech is one of the leading sectors in southern California.

Mr. Rieger, who holds a Ph.D. in organic chemistry and worked as a research scientist for 15 years before moving on to patent law, has worked mainly with small- to mid-size biotech and pharmaceutical companies. One client is in Phase 3 clinical trials on a new treatment for pulmonary arterial hypertension, a potentially fatal disease. Another client is working on asthma treatments for individuals who cannot use standard inhalers.

Mr. Rieger said the law field's involvement with biotechnology is "a little of the chicken and the egg.

"As one expands, the other will go with it," he said.