

Attorneys Tune Into Life Science Law

by Laurie Burstein

The St. Louis legal community is tuning into the potential of biotechnology with more attorneys specializing in this growing area.

Life sciences attorney is a term that encompasses lawyers providing legal services to life sciences clients, which may include bioscience companies, hospitals and research institutions. Legal services include intellectual property and patent applications, Food and Drug Administration pharmaceutical and medical device clearance, health care reimbursement, and other regulatory issues.

Commerce Magazine spoke with several St. Louis attorneys who specialize in life science law to find out more about this growing practice.

Tara Nealey

Polsinelli Shughart

As a member of the science and technology practice group at the law firm of Polsinelli Shughart, Tara Nealey focuses on advising clients with intellectual property questions related to life science research.

Dr. Nealey has a Ph.D. in neurophysiology which helps her work with clients from start-up ventures to Fortune 500 companies in



Tara Nealey
Polsinelli Shughart

developing patents, licensing and long-term strategies. She has been a patent agent since 1997 and a patent attorney since 2001.

"I work with individual inventors all the way up to Fortune 500 companies, as well as research institutions and universities," she explains. "We often work with inventors to help them create an overall business strategy."

She continues, "In the area of patents, we help inventors create a real piece of property that can be bought and sold. With licensing, we work out the legal terms for paying for the rights to use the property."

Dr. Nealey gives an example of her work with a local Fortune 500 company who develops RNAi molecules and products. Her role was to evaluate all the patent applications and advise the client along the way for securing licenses. The company was able to move forward with a full product line using this new technology. She also recently assisted two start-up companies in securing the intellectual property protection necessary for successful venture capital funding.

Some challenges in the life science legal field Dr. Nealey mentions includes the long process and high cost of pursuing patents today. More companies are trying to create

value with the patents they have rather than seek new ones she says. Clients are also filing fewer patents in foreign locations which can also be costly.

Another challenge here in the Midwest is securing funding for start-up companies, however the new administration appears to be committed to science and technology and stimulus dollars are expected to come to Missouri Dr. Nealey says.

As both a scientist and an attorney, Dr. Nealey says she really likes getting in on the ground floor of new discoveries and helping clients bring their discoveries to the marketplace.

"What I like about practicing life science law is that I get to see cutting-edge research and technology up-close. I'm constantly learning about new discoveries that most people don't know about," she comments.

Dr. Nealey adds, "We help our clients bring their discovery to the marketplace in all kinds of different ways. We work with them on how to leverage their discovery not only with patents, but with corporate, finance and regulatory issues. We really become their business partner."

Powell Carman

Bryan Cave

Powell Carman is a partner in the Life Science practice with the law firm of Bryan Cave. He has practiced law for 21 years, with the past 10 years specializing in life sciences.

As general counsel for life science companies, Carman works with venture-backed companies to advise them on the corporate side of their business including licensing transactions, fundraising, governance, board matters, and mergers and acquisitions.

"Life science law is anything that deals with health and wellness in human and animals. It encompasses everything from nutrition to healthcare therapeutics and diagnostics, as well as the healthcare system at large," Carman says.

At Bryan Cave, Carman works closely with attorneys who handle intellectual property functions. On the IP side, attorneys deal with preparing and prosecuting a company's patents. Carman is on the business side which involves raising money and making deals with intellectual property.

Carman is general counsel for the Missouri Technology Corporation, a non-profit organiza-

tion that recruits agriculture and biotech companies to the state. They founded the Missouri Venture Fund which invests in food, energy and health companies based in Missouri.

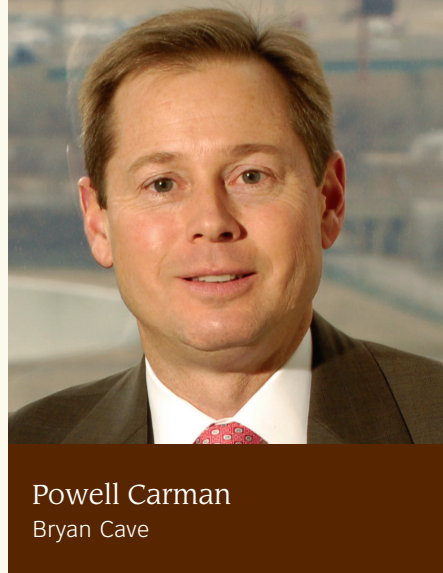
"This is the most exciting 'Missouri-centric' thing that is happening in life sciences. The Missouri Venture Fund focuses on companies and technology developed right here at home."

As general counsel, Carman helps the Missouri Technology Corporation with transactions when they make grants or awards to start-up companies. He also works with 20 life science clients both in Missouri and outside the state. Clients include agriculture clients and food ingredient companies.

Carman describes a success story with a client who developed a novel approach using a bio-pesticide using a totally green solution, replacing older toxic products. The client was on the verge of bankruptcy when new management was brought in and Carman became legal counsel. Carman helped attract investors and work through regulatory approv-

als with the EPA along with Bryan Cave's Washington, D.C. office. The product will be on the market by the end of this year.

Regarding the impact of life sciences and practicing law in this area, Carman comments, "This is technology that we can leave to our



children and grandchildren so that they have a better world. What can be better than helping to make our world a healthier place?"

As for the future of life science law, Carman says changes in the regulatory environment both in the healthcare delivery and payer systems, as well as likely changes within the FDA food and pharmaceuticals inspection system, will certainly have legal ramifications.

"With all these changes coming in the regulatory environment, there will be new regulatory issues that clients will need to have interpreted. I think over the next few years the whole regulatory scheme for life sciences will change dramatically," Carman says.

David Massa and Ken Solomon Gallop, Johnson & Neuman

As attorneys at the firm of Gallop, Johnson & Neuman, David Massa specializes in the healthcare and life science practice, while Ken Solomon is in the intellectual property practice group. They counsel clients in bio-



David Massa
Gallop, Johnson & Neuman



Ken Solomon
Gallop, Johnson & Neuman

technology, pharmaceutical, chemical and other technology-related industries.

Intellectual property is the fastest growing sector of the legal profession today.

IP attorneys' expertise includes drafting and prosecuting a wide range of intellectual property agreements, and preparing patentability, validity and infringement opinions on behalf of clients.

With more companies needing to protect and leverage their assets, as well as deal with growing regulatory issues, Massa and Solomon say their practices have grown significantly. Four attorneys practice life science law, while the IP practice has doubled in the last year and a half with 10 attorneys.

Solomon says he looks at a client's business plan as well as the nature of current and potential patents. He has more than 25 years of experience as a patent and trademark attorney and represents clients in St. Louis including Monsanto, Mallinckrodt Inc., Solutia Inc., Washington University and University of Missouri, as well as clients throughout the U.S. and internationally.

"As we see a change over from chemical-based technology to the biological-based technology, along with the growth of generic drugs, it is opening up the field to whole new set of patents and regulations, making IP a huge growth area," says Solomon.

Massa adds, "We really have to have a good understanding of our clients' business and growth plans. One of the really fun aspects of our job is counseling clients from the start-up research and development phase, to when the

client gets their first licensing agreement or brings a product to market."

As for future trends, Massa says there will be greater and stricter regulation both at the federal and state levels for clinical trials of drugs and medical devices.

Massa says the most important part of being an attorney in the life science field is helping clients grow. "Our job is to facilitate the growth of our clients. To see a client go from a start-up to becoming a stable company with a steady revenue stream makes our job as attorneys very satisfying," Massa says.

Rick Shear
Thompson Coburn

Rick Shear was the chief intellectual property lawyer at Monsanto where he gained extensive experience in patent prosecution, licensing and litigation throughout the world during his 25-year career with the company. Now a life sciences attorney at Thompson Coburn, Shear uses his expertise to counsel clients in all aspects of patent law with a focus in the fields of chemistry, including agriculture and pharmaceutical chemistry, and biotechnology.

Thompson Coburn's Life Science Group has 10 attorneys, all with chemical and biotech backgrounds. Thompson Coburn's IP group has secured biotechnology-related patents directed to recombinant DNAs, antibodies, enzymes, and peptides that are useful in a variety of agricultural, therapeutic, and diagnostic applications.

In one case, Thompson Coburn secured

an extensive portfolio of patents related to discovery of viral therapeutics that has been non-exclusively licensed across the pharmaceutical industry and has generated significant licensing revenue for the client. Other patents obtained by Thompson Coburn directed to therapeutic proteins and antibodies have been licensed to key biotechnology companies.

"Life sciences and law practices in this area have really been growing over the last 15 to 20 years," Shear says. "Over the last five to six years, our firm has really strengthened our practice even more in this area."

Shear represents corporate clients including Monsanto, along with universities such as Washington University. He also counsels the biotech company ICL Performance Products LP in St. Louis and local start-ups such as Trace Botanics.

"We prepare and file patent applications for clients such as the Danforth Plant Science Center where they have ongoing research in which they have invented new products and processes. For example, we file patents for genetic technologies for preventing plant diseases," he explains.

Shear adds that life science attorneys also get involved in licensing negotiations, writing opinions with respect to the validity and infringement of patents and in litigation.

"One of the challenges in life sciences with respect to patenting is that companies seem to be held to a higher standard. Under the law, biotech inventions get a very high degree of scrutiny," Shear says. ■



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