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MCC INTERVIEW: Teresa Lavoie / Fish & Richardson

How a Patent Prosecutor/ Strategic Adviser Racks Up Wins

Building strong patent portfolios builds value in growing companies

***Teresa Lavoie**, a principal at **Fish & Richardson**, didn't start out planning to practice law. Her background is in science, and her first quasi-legal position was working as a patent liaison at a biotech startup before she decided to attend law school. But that was obviously a good career move. She's been working with startups ever since, and Lavoie has become one of the most sought-after life sciences patent attorneys in the world. The interview has been edited for style and length.*

MCC: Tell us a little bit about your background and your patent practice.

Lavoie: Like many IP attorneys who focus on the life sciences, I have a background in science – a B.S. degree in chemistry and a Ph.D. in biophysical chemistry. And like many of my peers, I realized that my love of science and writing was likely better suited to a career such as patent law than in academia or industry. My path, however, was unusual in that I started out in-house, as a patent liaison at a startup biotech company, rather than immediately attending law school full-time or working part-time as a patent agent at a firm while attending law school in the evening. That in-depth exposure to a fast-paced startup environment at that time in my career was absolutely critical to my desire and ability to build my current practice, which is focused on biotech and biopharma startups in major biotechnology clusters, including those in San Francisco, San Diego and Cambridge, Massachusetts.

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My focus on startups often means that many of the clients I work with have aggressive growth followed by rapid slowdown, as clients get acquired by larger companies or license out key portfolios. I've learned that you've got to enjoy the roller coaster ride and keep doing the absolute best job for your clients through it all. And they hopefully will come back to have you do it all over again when they move on to the next exciting opportunity.

MCC: Can you share some examples of recent successes that you've had for your clients in these sectors?

Lavoie: As a patent prosecutor and strategic counselor, I don't often get big "wins" that I can point to, such as major court decisions. However, major client funding events or partnering activities, while clearly reflective of the management expertise and the product value proposition, can nonetheless provide some indication of our successes in building high value strategic IP portfolios, since IP is a major component in any biotech due diligence. For example, we handle the IP portfolio of Loxo Oncology, which raised $138 million in January 2017 to continue its development of highly selective medicines for genetically defined cancers. Loxo was only formed in 2013, yet it already has two drugs in the clinic, and an impressive patent portfolio supporting its lead and backup oncology products. For another client, IFM Therapeutics, which raised $27 million in June 2016, we have been rapidly building its IP portfolio for drugs for the treatment of cancer and inflammatory disorders.

MCC: With the investment community so enamored of the biotech and biopharma industries recently, how has this influenced and changed the patent strategy you develop for these types of companies?

Lavoie: The timeline to either product approval or to a funding or an acquisition has reduced dramatically over the past decade. We've learned that on the IP side, we have to work much more quickly – but with the same emphasis on providing creative, substantively excellent and strategically focused portfolios for our clients. You've got to bring your "A" game to every client from the beginning. And while the experience can be exhausting, it's always intellectually thrilling and emotionally fulfilling. My clients are working with incredible dedication and focus to provide life-saving medicines to people who need them, and it is exciting and energizing to work side-by-side with them.

Teresa Lavoie, *Ph.D., is a principal at Fish & Richardson, where she focuses her practice on strategic patent counseling, patent prosecution and portfolio development advice for startups and emerging companies, and for academic and research institutions in the biotechnology and biopharma industries. She is based in Fish's Twin Cities and Silicon Valley offices and can be reached at lavoie@fr.com.*

MCC: You have spent the past seven years helping build the IP portfolio for your client Samumed, which was called "the most valuable biotechnology startup on the planet" by Forbes in May 2016. How important are patents to the value of startups and emerging companies? What advice would you give to companies that want to be the next "most valuable biotechnology startup on the planet"?

Lavoie: Before a company has a product approved, with an associated revenue stream and management track record for success, the IP portfolio can be seen as a proxy for the strategic thinking and scientific creativity of the startup team. While there is an impetus now to file quickly in order to address concerns under our first-to-file regime, you still need to map out your program research activities, including clinical development activities, and align them with your patent portfolio development in order to avoid missing important filing opportunities or cause yourself prior art headaches down the line. My advice often is to step back, take a breath and think about your portfolio on a macro-level. And do that every quarter or so, to ensure that the portfolio is moving in the direction of your current research and strategic business goals.

MCC: Working with biosimilar and biologic companies is another area where you have deep expertise. What are some of the key patent issues you are dealing with right now in this space?

Lavoie: As I previously mentioned, the timeline for product development in biotech has been drastically reduced, including notably so for biologics such as antibodies. There are a great number of very smart biologists working in the field who have brought the first and second and third generations of biologics to market and who are now "all in" on providing the next generation of biologics in record time. For biologics, addressing the scope of the case law as it pertains to patent eligibility remains a concern for both methods of use and compositions, as well as monitoring freedom to operate issues around the newer targets being identified.

In addition, biologic companies are just starting to wrestle with market entry of biosimilars, from both the legal and commercial standpoints. We saw a large increase in patent filings related to biologics over the past decade, as innovator companies attempted to build a patent wall to protect their blockbuster products, including in areas where innovators had not traditionally pursued much IP. These included protein production, purification, post-translational modification and formulation technologies. With the advent of post-grant review proceedings such as inter partes review (IPR), we are seeing biosimilar companies trying to knock out some of these "evergreening" patents in their attempts to simplify the ultimate "patent dance" that may occur before the biosimilar can get to market.

MCC: Academic and research institutions have their own unique set of challenges when it comes to earning revenue from their patented technologies. How do you help these clients be successful while still protecting their IP investment?

Lavoie: Because of the typically vast range of technologies, including non-life science technologies at any academic or research institution, it's often extremely difficult for a technology transfer office to invest the time, money and intellectual resources necessary to adequately pursue patent protection and commercial licensing opportunities for their technologies. We help these clients by triaging the wealth of input to their offices to determine which technologies are most viable from both patentability and commercial potential perspectives. Since we need to do our work on typically tight budgets, this type of strategic focus helps our clients maximize the return on their tech transfer budget investment. We also provide significant educational opportunities, such as seminars, webinars and boot camps, to academic inventors and tech transfer office personnel to help them compete from an IP perspective with organizations that have much bigger budgets.

MCC: How important are licensing deals to universities and research organizations? Are there alternative solutions?

Lavoie: Licensing deals are absolutely critical to most universities and research organizations, because they often do not have the money, infrastructure or expertise to bring an invention – particularly one with the potential to be truly disruptive to an industry – to market. The licensing revenue to the institution provides capital that can then be used to reward academic inventors. It can also be used to invest in and publish on basic research, which is typically the fundamental goal of any university and research institution. Some of them have developed translational research capabilities as well as entrepreneur training initiatives and programs. And these, in turn, have enabled those institutions to bring a concept much closer to the commercialization stage. Others have formed strategic partnerships with incubator organizations to help their technologies move beyond the university setting.

MCC: You have a fascinating niche practice representing emerging food technology companies that are leading the "clean foods" revolution. We would love to hear about these food clients and how the work you do for them relates to your biotech and biopharma work.

Lavoie: This sector has been so much fun to work with. These companies and inventors are using (and developing) the most cutting-edge protein chemistry, molecular biology and chemistry technologies in pursuit of their mission, which is to make the global food system more sustainable and to reduce the environmental impact of food production – while not compromising on the flavor and desirability of their products. For one client, Impossible Foods, which has "removed the cow from the burger" in its quest to perfect plant-based meats, we have worked on expanding and strengthening its patent portfolio, which ranges from flavor and mouthfeel chemistries to high-yield protein production and purification methods. Other clients in the space include Ava Winery, which is investigating how to make wine without grapes, and Perfect Day Foods, which produces "animal-free milks."

All of these clients have the same creativity and problem-solving attitudes of my more traditional biotech clients, which are typically developing small-molecule and biologic drugs. We face many of the same IP challenges in developing the clean food portfolios as we do for our more traditional biotech clients. But there's one important difference: I get to taste-test these clients' products when I visit.