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Joys and Challenges of IP Practice at the Intersection Of Science and Business

▸ Dr. Daniel W. Clarke, Dr. Christopher Cowles and Dr. Richard Emmons talk about their experiences at Burns & Levinson representing life sciences clients.

CCBJ: Tell us about your background and your practice.

Dr. Daniel Clarke: I earned my Ph.D. in molecular microbiology before becoming a lawyer. For almost 13 years, I've focused my practice on patent preparation, prosecution and due diligence, primarily in the biotechnology and life sciences areas – immunology, microbiology, genetics, oncology, molecular diagnostics, molecular biology, medical devices, tissue and cell engineering/regeneration and small molecule therapeutics, among many others.

Dr. Christopher Cowles: I have 15 years of patent prosecution experience in the life sciences space, including both firm and in-house counsel experience. My practice is entirely life sciences focused with a blend of both corporate and academic institution clients. Prior to entering the law, I performed my Ph.D. work in cell biology at the University of California, San Diego, and then performed postdoctoral research in genomics as a Damon Runyon fellow at the Whitehead Institute at MIT. My specific areas of expertise include oligonucleotide therapeutics, oncology, diagnostics, antibody, microbiology, virology, cell biology and genomic technologies.

Dr. Richard Emmons: I earned my undergraduate degree in ecology, and spent many years doing field research on loggerhead sea turtles. During college, I was awarded fellowships from the Pew Foundation and the Howard Hughes Medical Institute to work in a physiology laboratory and a developmental biology laboratory, respectively. These experiences shifted my interest from macro-biological to micro-biological science, and I went on to earn my Ph.D. in developmental biology at the Washington University School of Medicine, followed by a postdoctoral fellowship studying epigenetic mechanisms of gene regulation at Harvard Medical School. My scientific career spanned nearly 20 years and provided me with hands-on training in a wide variety of scientific disciplines, including electrophysiology, classical and molecular genetics, molecular biology, biochemistry, cell biology and immunology. Now, my practice includes a wide variety of intellectual property issues in the life sciences, medical device and mechanical/electrical art areas.

Daniel Clarke, Ph.D. is a partner in the Life Sciences and Intellectual Property groups at Burns & Levinson, where he counsels biotechnology and life sciences clients in strategic patent procurement, IP due diligence and worldwide prosecution. He is based in Boston and can be reached at dclarke@burnslev.com.

How does that background apply in your legal work?

Cowles: It helps tremendously to be fluent in the language that client inventors and companies use. I'm fortunate in that I was able to learn a gamut of different technologies at the bench that were nascent and cutting-edge before transitioning into the law.

My colleagues and I here at Burns often draw upon our breadth and depth of scientific training to connect an area of research experience from our graduate work or postdoc with a client's area of invention. The scientific connections – which are not only about inventive subject matter but also in the realm of interpersonal connections and scientific fluency – ultimately improve the quality of the work product we are able to provide to our clients, and help make us efficient in serving our clients' real needs.

Who are some of your clients, and what are the most challenging patent issues you've tackled for them?

Clarke: I've worked with startups, academic and nonprofit institutions, and midsized and large biotechnology companies, as well as their licensees. Helping clients strategi-

cally manage their patent portfolio in a way that is congruent with ever-changing business objectives is the most enjoyable and most challenging aspect of my patent practice. We thread the needle by distinguishing a client's invention from competitor products, while at the same time preserving patent rights that are valuable in the marketplace.

Cowles: Academic institutions and industry clients each have their own unique challenges. For academic clients, the timing of a professor's or scientist's public presentations or publications can create tight deadlines for preparing new patent applications – although it can be fun to dive into an area quickly, with intensity, to produce something that succeeds in protecting our client's interests. For industry clients, IP due diligence projects are often both incredibly interesting and intense and challenging. To play a role in a biotech company's funding, partnering or merger and acquisition efforts is very gratifying.

Emmons: I work with a broad array of institutional and corporate clients. Gene therapy is one of the most challenging areas that I work in because there are so many moving parts that need to be assessed from an IP standpoint, such as construct design, delivery vehicle choice, packaging methods and manufacturing methods. These all need to be strategically assessed in unison.

What unique issues do academic and research institutions contend with, and how do you help them protect their IP investments and earn revenue from their patented technologies?

Clarke: Universities and hospitals provide a platform for the creation of new technology. However, these institutions often do not have the resources for technology development and commercialization. In many cases, the institution will partner with the individuals who invented the technology to either form a new company or identify a company that is interested in developing and commercializing the product or process. We help our institutional clients protect their IP investments and earn revenue through due diligence, drafting patent applications (which, when granted, provide exclusive rights to the claimed subject matter for a limited period of time) and licensing deals. Academic and research institutions typically strive to non-exclusively or exclusively license the new technology, including the patents, to the spin-off or interested company in exchange for revenue provided to the institution.

Cowles: Academic and research institutions are uniquely wide-ranging in their technological efforts, yet are often so far removed from having a refined drug or commercial product in sight that we have to project where the life sciences industry will be in 10 to 20 years. Our primary goal remains protecting the client's interests/inventions, yet we also must avoid placing anything too conjectural into initial patent applications. Such statements can risk actually harming the scope of protection available to, for example, a licensee, or even to the academic inventors themselves, once there is actually a more refined drug or commercial product in play. Nonetheless, producing patent application filings for our academic clients is a significant part of our practice, because such filings allow them the best avenue for monetizing their inventive assets.

Richard Emmons, Ph.D. is a partner in the Life Sciences and Intellectual Property groups at Burns & Levinson, where he assists life sciences, medical device and mechanical arts clients with IP due diligence, IP licensing, and patentability, infringement, validity and freedom-to-operate analyses. He is based in Boston and can be reached at remmons@burnslev.com.

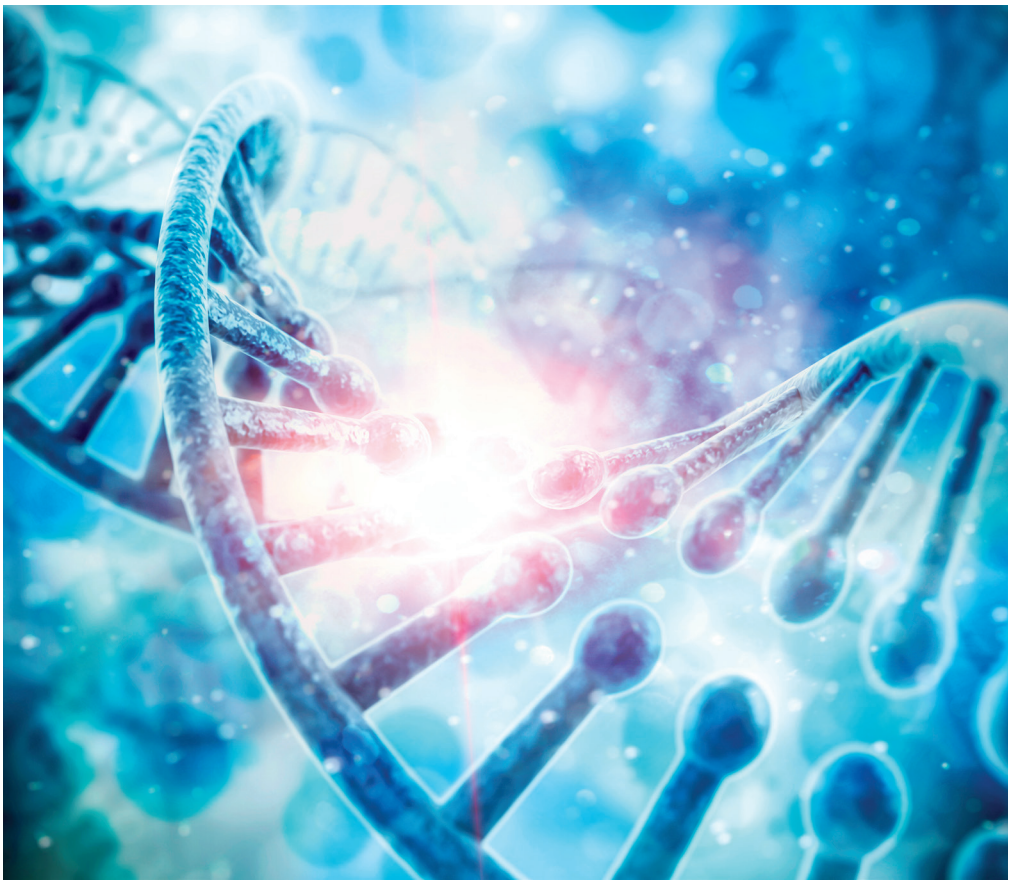
Christopher Cowles, Ph.D. is a partner in the Life Sciences and Intellectual Property groups at Burns & Levinson, where he focuses his work on biotechnology patent preparation and prosecution, domestic and international IP portfolio management and IP due diligence. He is based in Boston and can be reached at ccowles@burnslev.com.

Emmons: Academic and research institutions face many challenging issues on the IP front, not the least of which is the need to balance the institution's desire to provide IP protection for very early stage technologies with the faculty's need to publish and present their research. I work with scientists to ideate their research, which helps ensure that provisional patent applications are directed to all of the scientists' key ideas. I also work with the scientists to monitor the progress of their research after the provisional application has been filed so that we may make informed decisions about whether or not to file following provisional applications. In this way, we can ensure that the academic institution has rock-solid IP protection for the technology.

Your team has significant experience handling IP due diligence and freedom-to-operate (FTO) analyses for startups and emerging companies. What does this work entail and why is it so important?

Clarke: It is crucial that startups and emerging companies perform IP due

diligence to identify any competitors that might have already carved out exclusive rights to technology in their space. An FTO analysis entails searching patent literature for issued patents or pending applications with claims that might cover a product or process of interest to the company. We also help our clients with patentability analyses, which involve reviewing both patent and non-patent literature to assess the likelihood of receiving a patent based upon their technology.



Cowles: The IP due diligence and FTO work that we perform for our industry clients tends to involve directed reviews of the client's activities and IP protection, as well as the activities and IP protection of a potential partner and/or competitor practicing in the same or similar area. (Often, the lines between potential partner and competitor are fluid in the biotech industry.) For a smaller client seeking to raise funds and/or partner, IP due diligence will almost always involve establishing our client's FTO in their commercially directed practices – because some manner of assurance that a client company actually has FTO tends to be critical for valuing the company's IP assets. It is always preferred to identify IP and FTO risks relatively early on in a diligence process so that such information can be wrapped into the broader negotiation process with some degree of clarity.

Emmons: This type of diligence work requires an in-depth understanding of the IP space as it pertains to a client's specific technology. Generally, the FTO analysis requires searching and assessing the IP landscape for a client, in determining whether there is any IP the client would need to consider licensing, or whether they have clearance in the area. This is very important because it provides the foundation for all strategic IP development and portfolio management.

Looking ahead, what challenges and opportunities do you see for the life sciences industry?

Clarke: In April 2018, the U.S. Patent and Trademark Office [USPTO] published a memorandum that attempts to clarify the complex issue of patent-eligible subject matter [35 U.S.C. § 101] in view of the Federal Circuit's recent *Berkheimer v. HP Inc.* decision. This should make it more difficult for patent examiners to support a rejection on the grounds of patent-ineligible subject matter. It will be interesting to see how the USPTO continues to interpret subject matter eligibility in accordance with prevailing jurisprudence, as this has the potential to either stifle or spur innovation in the life sciences industry.

Emmons: I recently presented an IP workshop at a gene therapy conference, and everyone was talking about the recent FDA approval of Spark Therapeutics' direct gene therapy product Luxturna, which represents a significant turning point in the gene therapy field. A key challenge in this area will be the techniques and methods required to scale up manufacturing processes for gene therapy reagents and how these challenges will interface with pricing strategies. ■