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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Q&A With Hodgson Russ' John Lopinski

Law360, New York (April 01, 2013, 12:39 PM ET) -- John D. Lopinski, Ph.D., is a partner in Hodgson Russ LLP's Buffalo, N.Y., office. His practice includes patent and opinion work, and strategic development of patent portfolios. He specializes in molecular biology, genetics and immunology, focusing on complex immunotherapies, cancer biology, and diagnostics and therapeutics for a wide range of human and animal disorders. He provides regular advice to university technology transfer offices, as well as private sector clients that range from publicly traded corporations to technology startups and university spin-offs. He is an active member of the Association of University Technology Managers, and a trustee for the Leukemia & Lymphoma Society, Western and Central New York Chapter, where he serves as chairman of the patient services committee.

Q: What is the most challenging case you have worked on and what made it challenging?

A: We had a protracted dispute with a patent examiner about whether a priority claim to a provisional patent application should be accorded. The challenge involved showing what one skilled in the art would understand about the claimed technology at the time the provisional application was filed. It was a frustrating experience because it is axiomatic that a patent application does not need to — and generally should not — describe what is already well known in the art. In this case, I believed it was indisputable that the provisional application provided an adequate basis for the claims, and it was an issue that should not have even been raised during examination.

The matter was ultimately resolved favorably, but with some needless prosecution history. This type of scenario will have even greater significance with changes to a first-inventor-to-file system in the U.S. After this change, priority to provisional patent applications will frequently become a kind of “coin of the realm” to preclude, for instance, citation of third-party references that may be published after filing of the provisional application, but before the date the nonprovisional or Patent Cooperation Treaty application is filed.

Q: What aspects of your practice area are in need of reform and why?

A: The U.S. Supreme Court’s decision in Mayo Collaborative Services v. Prometheus Laboratories called into question the validity of a large number of issued patents, and has created uncertainty for the fate of

an untold number of pending patent applications that cover diagnostic methods. The decision also has broad implications for the medical diagnostics industry generally, and has certainly made an immediate impact on patent application filing strategy, licensing negotiations and litigation. However, it is well within the purview of Congress to create statutory language so that these important types of inventions can return to their long-held status as patent-eligible subject matter.

This was obviously an issue of great debate, and reasonable minds can disagree, but in my view it is better public policy to allow patent protection for diagnostic tests than to not allow it. This is especially the case when one considers not only the tremendous scientific effort that goes into initially discovering a diagnostically interesting marker, but also the series of events that must take place to validate the marker as clinically useful, to proceed through appropriate regulatory review where required, and to develop manufacturing and distribution channels so the test can actually be performed on a scale that benefits the public.

Add to these complexities the lengthy process for approval of reimbursement by health insurance providers and it becomes apparent that bringing a new diagnostic test to market in a way that makes economic sense requires vastly demanding human and financial efforts that go well beyond the initial scientific discovery. It should be self-evident that these are easier risks to take when a patent is in place. I also think the plain reality that patents expire in 20 years from their filing dates (except for certain types of extensions) does not receive enough consideration when, presumably, humans will be around for a lot longer than 20 years and will be able to realize the benefits of the test for as long as it remains useful.

Q: What is an important issue or case relevant to your practice area and why?

A: In the Myriad case, the Supreme Court is preparing to answer the question: Are human genes patentable? This question is the subject of much commentary, and is underpinned by thousands of court documents detailing legal and scientific complexities it involves. The court's answer will impact many patents and patent applications, but the reality is that humans are all genetically very similar, DNA sequencing technology has advanced at an incredible rate, and it is now likely there are not many novel human "gene" sequences left that would warrant an investment in patent protection.

Further, most human DNA does not exist in the form of "genes" as the term is conventionally understood, so it is not clear what relevance a square answer to the question will have for "non-gene" genetic material, like miRNA, noncoding DNA, and other types of nucleic acids that an informed court should not consider to be a "gene." What is troubling is the potential for the justices to proffer dicta that does not answer the question, but will act as a guide for other courts to deem all isolated nucleic acids to be nonpatentable. The emotionally charged nature of the "genes" that are recited in the Myriad case is understandably an issue of great interest to many different stakeholders, and the decision will be met with widespread praise and criticism, no matter which way it goes.

Q: Outside your own firm, name an attorney in your field who has impressed you and explain why.

A: Lorrie Turner was a litigation and trademark associate in our firm years ago. She left to become in-house counsel at a large, privately held company, and then became general counsel of the New Era Cap company. New Era is based in Buffalo, N.Y., but has locations across the globe, and is best known for making caps that bear the trademarks of many major league sports teams and other significant brands. This is an unusual career trajectory because most in-house attorneys who have significant grounding in IP tend to report to the general counsel, rather than actually taking that position. So, I really admire Lorrie's ability to use her significant trademark expertise as a springboard to attain the highest-ranking legal position in a global company, where trademark law is just one important component of its complex business.

Q: What is a mistake you made early in your career and what did you learn from it?

A: I filed a PCT application for a foreign company at the U.S. receiving office. After some time, a communication from the World Intellectual Property Organization's International Bureau arrived — the application had been forwarded there. A review of the transmittal documents showed that the only inventor on the application was listed as a citizen of the same foreign country as the applicant, but the inventor was in fact a U.S. citizen. This was important because U.S. citizenship provides a basis for filing in the U.S. receiving office.

After some anxious communications with WIPO, we had confirmation that the application was in good standing. So, not noticing the inadvertently incorrect citizenship listing (a two-letter difference) cost time and effort to ensure there were no material consequences. I learned from this that no matter your station in a law firm, whether the firm is large or small, you should be able to make the coffee and refill the printer paper — no one is too important, too smart or too highly compensated to do those type of things once in a while. To put it another way, it is useful for every attorney to be very familiar with formalities and the "little things" that nonattorney professionals usually handle because, as with life in general, the so-called little things can make a big difference in the practice of law. (I hope there are no typos in my answers!)

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