Life Sciences

This month, *Lawyer Monthly* focuses on Life Sciences and the legal issues surrounding it, by speaking to Eldora L. Ellison, Ph.D., Partner in the Biotech/Chemical and Litigation Groups of Sterne, Kessler, Goldstein & Fox, P.L.L.C. She has twenty years of experience in obtaining, challenging, and defending patents. Eldora has served as lead counsel in approximately 20 inter partes review proceedings (IPRs), drawing on her multidisciplinary experience in patent interferences, patent prosecution, and patent litigation.

Please introduce your role.

The majority of my cases are on behalf of biotechnology and pharmaceutical companies, which makes good use of my Ph.D. in biochemistry, molecular and cell biology. Sterne Kessler is an intellectual property specialty firm with more than 150 professionals, nearly all of whom are registered to practice before the USPTO, including 60 Ph.D.s. Since it was founded 35 years ago, Sterne Kessler has remained at the cutting edge of patent law and technology.

What are the most common types of case you deal with within the Life Sciences sector?

Currently, IPRs occupy the majority of my time, as that is a natural transition from handling patent interferences for many years before the same body of judges. As an example, I served as lead counsel in the first IPR on a pharmaceutical drug product. Our client was also involved in concurrent ANDA litigation on that drug product. That IPR was particularly noteworthy because a U.S. District Court had previously determined that the patent was not invalid but was infringed by a different party. Nonetheless, the USPTO found that we were reasonably likely to prevail in showing unpatentability over the same prior art that had been asserted in district court. Through the concerted efforts of our integrated IPR and litigation teams, our client ultimately settled both the IPR and the litigation. Since then, stakeholders in the pharmaceutical industry have increasingly made use of IPRs, particularly in the context of ANDA litigation.

What are the common challenges faced by your clients when involved in Life Sciences?

Recent evolutions in the law have created uncertainty for clients who seek to secure and maintain patent protection for their critical products or future products. For example, court decisions in cases such as Mayo v. Prometheus and AMP v. Myriad Genetics raise new questions regarding what is patentable. The new inter partes review proceedings and future post-grant review proceedings leave patent owners vulnerable to further patent challenges. But for parties who seek freedom to operate, these new developments in the law create new opportunities. And, of course, clients are challenged to respond to these developments in the law while maintaining limited legal budgets.

How has/can your firm assist the client when such challenges arise?

Our multi-disciplinary teams of lawyers take a proactive approach to facing these challenges. Such actions span a range that includes:

- strategically drafting and prosecuting patent portfolios in light of the most recent case law and with an eye to mitigating potential later challenges.
- conducting thorough reviews of existing portfolios for strengths and weaknesses.
- aggressively representing clients while challenging and/or defending patents before the USPTO and district courts.

We have the in-depth patent experience, real-world litigation experience before district courts and before the Patent Trial and Appeal Board, and a deep bench of scientifically trained lawyers to assemble a well-rounded team to meet the variety of challenges our clients face. And we bear in mind the business objectives and budget constraints of our clients when developing client teams and strategies.

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Have there been any recent legislative changes regarding this sector?

The America Invents Act brought about a host of changes that affect stakeholders in the Life Sciences, both those seeking to obtain patent protection under the new laws and regulations, and those who are involved in patent challenges under the new laws. Also, the Biologics Price Competition and Innovation Act of 2010 will create new legal challenges for biotech companies in that it provides a mechanism for competitors to bring to market "biosimilars" that compete with innovator drugs. In the face of such challenges, having a strong patent portfolio will be essential, particularly as competitors will make full use of the various available mechanisms for challenging patents.

How can clients avoid the potential pitfalls of the laws which surround this industry?

It is increasingly important to obtain well-crafted patents that provide a full range of patent protection. And "evergreening" strategies play a very significant role. But it's also important to work with the right team of attorneys that understand the new laws and have in-the-trenches experience in operating under them. For example, while many firms believe their district court experience may make them suited for handling IPRs before the PTAB, the reality is that these proceedings are much more akin to patent interferences than they are to district court litigation. Our experience in handling more than 65 IPRs has been enhanced by our prior experience in handling more than 50 interferences. And through our extensive experience in IPRs, we have learned nuances of IPR practice that are not apparent from the laws and regulations.

Do you foresee the need for legislative change in the next 12-24 months, if so why?

As the AIA is implemented and adjudicated, there may be a need for further refinement of the patent laws. Some stakeholders believe that the legislation has not adequately fulfilled Congress's intent that it provides a cost-effective alternative to district court litigation, particularly since the vast majority of patents involved in IPRs are involved in concurrent litigation. Also, some patent owners believe that the playing field is not level in post-grant proceedings at the USPTO because of the limited opportunities to make arguments or claim amendments. So, it may take some time to see what impact, if any, this perception of an uneven playing field has on innovation and whether further modifications of the law are needed. **LM**

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