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USA EXPERT INSIGHT INTO BIOTECHNOLOGY



The Biotechnology industry is fast-paced and full of regulatory challenges. To find out about these challenges and the other issues surrounding this sector, *Lawyer Monthly* speaks to Eldora Ellison, Ph.D. of Sterne, Kessler, Goldstein & Fox PLLC. The firm is a full-service intellectual property specialty firm with approximately 150 professionals, more than half of whom hold masters degrees or Ph.D.s in science or engineering.

How much of an impact has the America Invents Act had on the Biotech industry?

The AIA has had a very significant impact on the biotech industry. In my opinion, the AIA has increased the complexity of obtaining patent rights, and it has increased the uncertainty patent owners feel in maintaining those patent rights. The shift to a first-inventor-to-file system and the new definition of prior art have changed the strategies that patent owners implement in obtaining patent protection. And the advent of IPRs has had a tremendous impact on the industry. The mere possibility of facing an IPR affects a company's litigation and patent prosecution strategies. And the possibility

of IPRs creates ongoing uncertainty for patent owners, particularly for patents that relate to lucrative products in a competitive marketplace. IPRs have been quite popular with potential challengers because they can provide negotiation leverage for the challenger, and the PTO has cancelled a high percentage of challenged patent claims. The AIA also ushered in post-grant review proceedings, and it's just a matter of time before those proceedings realize their full potential.

Has the passing of the Act made your job more difficult, or easier?

I wouldn't say that the AIA has made my job more difficult, but it has definitely made it more interesting. Change invariably

creates uncertainty, and the AIA has thus created new challenges both for the industry and the lawyers. But change also creates opportunities, and our clients have sought to maximize such opportunities, whether it be by filing IPRs or by seeking Track 1 (i.e., expedited) examination of their patent applications. The changes in the law have increased the need for counsel that understands how to develop a strategy that coordinates patent prosecution, traditional litigation, and the new post-issuance PTO proceedings.

Such a fast-paced industry moves rapidly; how can legislation keep up, if at all?

Certainly our legislature must stay in tune

with how the AIA impacts the business community. While there's a need to ensure that patent quality is high, it's also important that our patent system continue to promote innovation by providing meaningful patent protection. While the AIA brought about sweeping changes to our patent laws, it was many years in the making. So, additional changes will need to be made more incrementally to fine tune the current system and avoid legislative gridlock.

long-term relationships with clients is more important than accepting every project that comes down the pike.

What are the legal remedies available to Biotech companies who are involved in a patent dispute? How can your firm help?

Any company involved in a patent dispute must consider the possibility that the patent will be challenged in an IPR or PGR

and strategies for achieving their particular business objective. Not only can we help clients with any of the available legal remedies, we have boots-on-the-ground experience in helping clients with parallel proceedings, e.g., a concurrent IPR and district court litigation, or concurrent ITC investigation and IPR. And, we can help patent owners understand and maximize their opportunities to secure meaningful patent claims at the PTO. This is particularly important given the difficulty in amending claims in IPRs and given the ripple effect of patent-owner estoppel for a patent owner that loses or abandons claims in an IPR or PGR. Importantly, we help clients be proactive in protecting their important patent estates. Rather than wait for someone to challenge a patent, we conduct a forensics analysis on our clients' important patents and work to address concerns in advance of a formal dispute.

Is there anything else you would like to add?

We operate in a new era of patent law, and the needs of the biotech and pharmaceutical industries have continued to evolve. Any company that operates as though it's business as usual will miss out on opportunities and leave itself vulnerable to its competitors. **LM**

“Any company involved in a patent dispute must consider the possibility that the patent will be challenged in an IPR or PGR proceeding at the PTO.”

What are the main challenges you face within your day to day work? How do you navigate them?

We spend considerable time and effort addressing ethical and business conflicts of interest. Plenty of well-intentioned firms have found themselves in a "pickle" due to real or perceived conflicts of interest. We try hard to avoid them. To this end, we seek to communicate clearly with our clients and other parties regarding the scope of our representation and views on conflicts, and we work hard to understand the business and ethical implications of our client representations. Building deep,

proceeding at the PTO. Additional options also exist at the PTO, though they are less commonly used. The company must also consider the possibility of traditional district court litigation; and litigation before the international trade commission has increasingly become a possibility in the biotech and pharmaceutical industries. We advise clients on the best legal options

