Jane Massey Licata

Founder
Licata & Tyrrell P.C.

66 E. Main Street, Marlton, NJ 08053
Tel: 856-810-1515 | Fax: 856-810-1454
Email: jmlicata@licataandtyrrell.com
www.licataandtyrrell.com

In this insightful interview, Jane Massey Licata of Licata & Tyrrell P.C. shares her thoughts on her multidisciplinary approach to tackling the legal complexities of cutting-edge technologies. Jane offers us a deep dive into her world - where technology races ahead of the law, and the art of legal strategy becomes a crucial tool for navigating this uncharted territory. From shaping laws and public policy to advising on data privacy and ethics, her work reflects a unique blend of scientific rigor and legal acumen.

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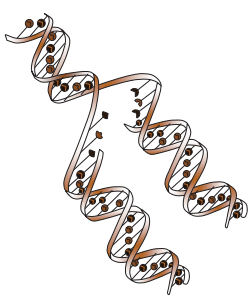

Q Jane, could you provide our readers with an overview of your work in AI, regulatory matters, and IP in the biotechnology and medical fields? How has this multidisciplinary expertise shaped the philosophy of Licata & Tyrrell P.C.?

The common factor in all of our work is that technology is often significantly ahead of the law, and we help shape the law and public policy. For example, molecular diagnostics raised not only the question of how to patent such an invention but also questions about genetic privacy and sharing of such information and the regulation of such products as medical products. In the area of AI, we first engaged with AI-enabled technology as software as a medical device and now work with many different products and systems in all aspects of healthcare and health & wellness applications. In addition to the IP and regulatory aspects, I also advise in the area of data privacy and ethics. The nature of the cutting-edge, paradigm-shifting technology we work with requires thinking about and developing a thoughtful, overall strategy. There are often many competing considerations, so we must look for the lynchpin and then build an approach around that. For example, is the market regulated, and if so, how can that be used to advantage? Is there a relatable legal principle that can be built upon or that needs to be distinguished? What is the technological and competitive landscape? Technology can be tools or platforms that can address many needs and are relevant in multiple markets. An interdisciplinary and creative way of thinking is helpful and

essential. When I was pursuing my Ph.D., I was incredibly fortunate to have a very interdisciplinary doctoral committee that included an organic and natural products chemist, a microbiologist, and an early adopter of computer analytics for exploring complex biochemical relationships. My post-doctoral work was with a remarkable woman who appreciated the role of science in shaping policy and law. My legal career has always been focused on building collaborations to solve complex problems that involve many disciplines.

Q What led you to specialize in such diverse yet interconnected fields as AI, biotechnology, and medical regulatory affairs? Was there a particular moment or case that defined your career path in this direction?

All of us were trained as scientists and came to appreciate that law is a necessary and powerful tool. Having a strong technical background is essential, but the key is to be a good communicator. We listen and learn from the creators and then develop ways to communicate with investors, business leaders, policymakers, lawmakers, regulators, and judges. It has been very exciting and challenging to work with many groundbreaking technologies such as molecular diagnostics and therapeutics, pharmaceutical formulations and delivery systems, cell therapies, tissue engineering, antibody technologies, environmentally sustainable systems, natural products and methodologies for nutritional supplements, novel foods and cosmetics, and AI-enabled products and systems.

Q Your firm offers a unique 'one-stop shop' service model, guiding clients from concept to market entirely in-house. How does this integrated approach provide an advantage to your clients, especially within the rapidly changing biotechnology and AI industries?

We have always appreciated that science and regulation need to go hand in hand. We work with our clients to develop a strategic approach at the outset to create and maintain a competitive position. This can mean building a strong IP portfolio and regulatory strategy in parallel. Sometimes, this also means creating new approaches and building relationships and collaborations to facilitate the introduction and adoption of paradigm-shifting technologies. In rapidly developing areas, creativity, agility, and the ability to think outside the box are essential; our decades of experience can offer valuable insights and perspectives to facilitate the process of bringing products to market.

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Q With the rapid advancement of artificial intelligence, how is your firm navigating the complex landscape of IP rights for those who have their rights infringed by AI creations? What challenges do you foresee in protecting innovation from AI?

AI raises many new legal issues and challenges which create uncertainty and risk. We are engaged in helping develop business and legal strategies and policies for many different kinds of applications and products. The dynamic nature of AI also makes conventional IP approaches less useful and requires thoughtful, and oftentimes novel approaches, to spur and protect innovation.

In response to the complexities of IP rights infringed by AI creations, our firm has adapted to the evolving legal landscape since our initial AI work in the 1990s. We initially focused on patenting automated systems but faced challenges as US

law evolved, leading us to pivot towards trade secret and contract protections, especially for software as medical devices. Recognizing the importance of data provenance and the changing dynamics of collaborations between academia, health systems, and technology companies, we've encountered new litigation and concerns around health data, privacy, and consumer protection.

Our approach includes developing strategies for a range of applications, recognizing that AI's dynamic nature requires novel methods to protect innovation. We've adapted existing laws and leaned into regulatory processes, addressing challenges such as data provenance and the complexities of collaborative research. By teaching and contributing to discussions on AI in healthcare law, we stay at the forefront of navigating IP protection in this rapidly advancing field, reflecting our commitment to innovating within the IP realm for AI technologies.

What are some of the biggest challenges you face when navigating the complex regulatory landscape for new biotechnological product applications? How do you innovate within these constraints to ensure client success?

Many years ago, the issue was new, and different technologies and products required changes in the regulatory regime. However, the regulatory bodies are science driven and designed to develop and adapt. We have always engaged early and often with regulators and policy makers to facilitate the process.

Without breaching confidentiality, could you share a case study or example where your firm successfully navigated a client "from concept to market"?

Some of the most rewarding projects have been with technology that was created at a university or start-up. We have been involved with many biotechnologies over decades as they evolve from basic science to proof of concept through development and into commercialization. AI is much more diverse and now very fast-moving, so the timelines are much quicker. However, the common element, no matter how slowly or rapidly the IP and regulatory processes move, is thinking about the possibilities and risks presented on an ongoing basis and maintaining the dialog with our creators and makers. This work is hopeful and forward-thinking and continues to challenge and inspire me!

Finally, how do you stay ahead of the regulatory changes affecting AI and biotechnology?

We engage. We work throughout the innovation ecosystem. Working with many academic research institutions worldwide, start-ups, and growing companies, we understand the challenges of translating science into invention and/or proprietary applications and products. We screen technology for collaboration and investment opportunities. We also work in the merger and acquisition area, helping identify, evaluate, and validate opportunities. I teach in these areas and participate in task forces and panels. I love science and the law and am fortunate that my work involves the knowledge, skill, and passion that both require in collaboration with creators, visionaries, and changemakers.

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