MOVING AT WARP SPEED:
Are you ready to go to market?

EVENT PARTNER: Hogan Lovells

Hogan Lovells' IP and global regulatory thought leaders share actionable insights on equipping biotech companies for success before seeking funding

Even before the pandemic began surging around the world and the race began to come up with a COVID vaccine, biotech companies often operated in drastically compacted timelines. This focus on speed to get new breakthrough treatments to market has led to a number of legal challenges, however, including complications in the oversight of important regulatory and intellectual property issues, whether a company is looking to close a seed round or go public.

To explore some of the legal challenges Massachusetts companies, both small and large, face in today's ultra-competitive, fast-moving biotech sector, the Boston Business Journal recently assembled a panel of leading thought leaders from the Hogan Lovells IP and global regulatory teams for a video seminar entitled "Moving at warp speed: Are you ready to go to market?" Moderated by Hogan Lovells Boston office partner Kristin Connarn, the following are some of the key takeaways from panelists Robert (Bob) Underwood, partner, Boston office, Hogan Lovells; Scott Kaplan, counsel, Boston office, Hogan Lovells; and Larry Shumway, Intellectual Property Counsel, Flagship Pioneering.

Editor's note: The following excerpts from the panel discussion have been edited for length and clarity.

By The Business Journals Content Studio

What sort of things should companies be thinking about from a regulatory perspective prior to going to funding?

Kaplan: We always say that the most important thing is knowing your innovation and your indication. Global regulators, and particularly the FDA, view your development program through clinical trials, as well as ultimately your path to market. They're looking at it through a public health lens— who will benefit and what other treatments are available for those patients? So your path to market and consequently, your path to funding, can look very different depending on what you're targeting and how you're targeting.

What have you seen successful biotech companies doing to get ready for funding?

Shumway: Biotech companies are selling a dream, and to get to market, they need to [eventually] show data and plausibility to what they're selling. They have patent applications that are artfully crafted and laid out and that have at least a plausible chance of establishing a global patent estate.

Underwood: One of the things that we see quite frequently as due diligence counsel is an esoteric and highly complex patent portfolio that the target company has created. To Larry's point, it is very helpful when company's counsel is able to explain the portfolio, and how and why it's relevant to the planned business activities.

Shumway: From my perspective, I think about some of the counterpoints where things can go wrong with the deal, like when the target's people are being perhaps too opaque. If they don't seem like they've been thoughtful in how they've laid out their patent estate, if they haven't been thoughtful, from a global perspective, well, maybe this [application] will be good enough for the United States, but not for the Europe Patent Office.

What sorts of things are you seeing as challenges that are particular to biotech companies moving at warp speed?

KRISTIN CONNARN
Partner,
Hogan Lovells

Kristin A. Connarn leverages her background in biotechnology and cancer research to effectively guide her clients through strategic patent portfolio development and management. Her practice focuses on life sciences patent prosecution, portfolio development, and management in the biotechnology and pharmaceutical sectors.

ROBERT (BOB) H. UNDERWOOD
Partner,
Hogan Lovells

Robert (Bob) H. Underwood, Ph.D. draws on his in-depth experience establishing U.S. and international intellectual property (IP) rights and identifying and evaluating third-party IP risks to help his clients achieve their business objectives.

SCOTT KAPLAN
Counsel,
Hogan Lovells

Scott Kaplan helps pharmaceutical and biotechnology clients achieve and maintain compliance with complex Food and Drug Administration (FDA) requirements.

LAURENCE SHUMWAY
Intellectual Property Counsel,
Flagship Pioneering

Larry Shumway joined Flagship Pioneering in 2018 and works on intellectual property protection for companies in the Flagship enterprise. He holds a B.S. in Biochemistry and Molecular Biology from the University of Massachusetts, Amherst; a Ph.D. in Biophysics from Harvard University; and a J.D. from Boston College Law School.

Underwood: Moving fast in the patent office does a couple of things that help play into the narrative. It shows that your IP has been vetted. When the company is successful in getting a U.S. patent granted early that protects their product candidate, it can imply that they will also be successful globally. That can move the needle on valuation. It also puts the company in the best position to be able to obtain any type of extensions of patent term, should they become available.

The types of delays that we see now with these companies that are moving very quickly can be related to CMC manufacturing and compliance issues.

Kaplan: Companies need to make sure that their manufacturing process and test method development keeps pace with product development. We're seeing a more condensed development timeline and that's creating more risk. We've seen more issues where assay development—in particular for potency and identity assay—is holding up application submission and approval.

COVID has brought that to the forefront and really highlighted the importance of planning for the evolution of your CMC section from the beginning.

How are we seeing this spill over into the investor side of things with Operation Warp Speed and how things have changed within the last nine months or so with COVID, other than not a lot of face-to-face networking and handshakes for deals?

Shumway: Early on in COVID a lot of companies had to, out of necessity, make do with a smaller research and production footprint. That ended up pushing a lot of focus to areas that teams felt like they could work on. And that includes a wide variety of legal questions, such as IP and regulatory.

What other recommendations do you have for companies to put themselves in the best position for success once they have found an interested funding party?

Underwood: It's really about preparing for due diligence, so that the due diligence can proceed as quickly as possible. Momentum is important in any transaction, and investors and strategics do not like due diligence surprises that slow the process. Companies looking for funding should do the IP and regulatory work necessary to be prepared, and if there are some IP or regulatory issues be ready with a plan to address them. Deals are often completed when the company's science and business models are sound, even if there are a few legal issues and a plan to address them. Companies that do this, typically have the greatest success when they seek investment.

For more information, please contact Sara Essama, Senior Marketing and Business Development Manager at Hogan Lovells, sara.essama@hoganlovells.com

From top left: Kristin Connarn, Partner, Hogan Lovells; Bob H. Underwood, Partner, Hogan Lovells; Laurence Shumway, Intellectual Property Counsel, Flagship Pioneering; Scott Kaplan, Counsel, Hogan Lovells; and Carolyn Jones, Publisher & Market President, Boston Business Journal.