Supplement to the Los Angeles and San Francisco
Daily Journal
JULY 5, 2023

TOP HEALTHCARE LAWYERS 2023

Top 10 considerations for transactions involving alternative protein companies

By Matthew A. Ferry and Sarah Bloch

The alternative protein market has exploded to meet consumer demand for innovative alternatives to meat, dairy, and eggs that resemble and taste like their animal-based counterparts. The market was estimated in 2021 to be valued at over $14 billion (Alternative Proteins Industry Trend | Alternative Proteins Market Report 2021-2030 (emergenresearch.com)) and is poised to grow to at least $290 billion by 2035 (Alternative-Protein Market to Reach at Least $290 Billion by 2035 (bcg.com)). Alternative proteins encompass a wide variety of technologies, including plant-based milks, lab cultured meats, and bulk protein and specialty ingredients produced by precision fermentation and cell culture. New start-ups and established companies alike are vying for a slice of the alternative protein pie. Here are the top ten aspects they should consider when planning for and negotiating research and commercial agreements.

1. HAVE A CLEAR STRATEGY TO PROTECT YOUR BACKGROUND IP.
Every inventive step in the development and manufacturing process should be independently protected either as a trade secret or through patents, including any genetic constructs and cell lines, methods of scale-up and manufacture, and the final products. Trade secrets can be valuable but must be subject to reasonable secrecy efforts to be protected in court (Trade secrets / regulatory data protection | USPTO (uspto.gov)). Therefore, technologies that are reverse-engineerable from or detectable in products are typically better protected with patents.

2. DEVELOP A PATENT PROSECUTION STRATEGY EARLY.
Given the crowdedness of this space, it is critical to understand the prior art landscape early on. Patent applicants should identify compelling narratives showing how the invention is superior to the prior art and build these narratives into the initial patent application.

3. CONSIDER HOW SCALE-UP AND MANUFACTURING OVERLAY WITH IP STRATEGY.
Scale-up and downstream processing are notoriously difficult hurdles for cell culture and fermentation products. Companies may need to transfer certain compositions and processes to scale-up and manufacturing partners and should carefully consider how to best protect them. Filing patent applications before signing any transfer agreement can establish the technology as the company's background IP. Companies may also protect innovations as trade secrets with robust confidentiality provisions.

4. THOROUGHLY EVALUATE FREEDOM TO OPERATE (FTO) AND COMPETITIVE LANDSCAPE.
Some alternative protein companies have begun to assert their patent portfolios against competitors. As the field matures and patent assertion increases, alternative protein companies can minimize their risks by understanding the competitive landscape and their FTO and that of potential partners.

5. PRESSURE TEST POTENTIAL PATENTS FOR LICENSING IN DUE DILIGENCE.
Before signing an agreement to license a potential partner's patents,

companies should thoroughly pressure test the patents in question. Do they have strong claims that cover the relevant processes and products and effectively block competitors? Are the key claims truly enforceable, or are they vulnerable to attack if asserted? Broad, dominating claims can look impressive. However, if a thorough evaluation of such claims raises questions of validity, they may be of questionable value as they may not effectively block competitors.

6. CAREFULLY NEGOTIATE ALLOCATION OF IP RIGHTS.

Development, supply, manufacturing and distribution agreements may result in the creation of new IP or improvements to existing IP. Companies should carefully craft IP terms to minimize the risk that the counterparty later hinders the company's development, control and commercialization of its own products. Such provisions should include a present-tense assignment to transfer the IP to the company and a "further assurances" clause to require the counterparty to perform additional acts that may be necessary to perfect or evidence the company's ownership of the intellectual property. Even with customers, alternative protein companies should ensure that they can freely use customer feedback without obligation to the customer.

7. INCLUDE A STRONG SUPPLY OR PERFORMANCE OBLIGATION.

Recent supply chain disruptions have underscored the need for the supplier's commitment to supply products, but the level of commitment in agreements varies. Companies should negotiate to include a hard obligation not only to meet the forecasted amount, but to meet a reasonable increase. Companies should also consider requiring a safety stock of ingredients, a transfer or escrow of manufacturing know-how, and preferential treatment if the supplier is unable to supply products to its customers generally.

The COVID-19 pandemic and resulting supply disruptions elevated force majeure provisions from boilerplate to essential for scrutiny. Companies should seek to exclude foreseeable circumstances and events that could have been prevented with reasonable care. Companies may also consider termination for extended force majeure circumstances and require that necessary arrangements be made in advance, such as with a tech transfer or release of manufacturing know-how from escrow.

8. TAILOR CONFIDENTIALITY TO THE COUNTERPARTY AND THE TRANSACTION.

Companies should include an expansive definition of confidential information and include any derivatives generated by the counterparty based on the company's confidential information. Companies should also ensure that their agreements include the three core confidentiality obligations: (1) maintenance of the information in confidence, (2) non-disclosure, and (3) non-use for any purpose other than the specified purpose. If a company needs to disclose material trade secrets, the company should consider including heightened security protections and a duration lasting as long as the information is not publicly known.

9. PAY ATTENTION TO LIMITATION OF LIABILITY PROVISIONS.

Counterparties often insist on a waiver of consequential and indirect damages and an aggregate liability cap. But letting this apply across the agreement to all kinds of breaches can be a trap for the unwary. Some breaches like confidentiality may, by their nature, only give rise to consequential or indirect damages. Companies should take care to carve these out from the waiver.

10. MAINTAIN CONTROL OF CONTRACT MODIFICATIONS IN RESPONSE TO REGULATORY CHANGES.

Regulations rarely keep up with science and technology, and the alternative protein space is no exception. As the FDA's and USDA's regulatory frameworks continue to evolve, companies in this space can hedge by building flexibility into their commercial agreements. If, for example, new regulations materially alter the main commercial benefit of the agreement, the company should have the right to terminate the contract or at least renegotiate the financial terms.

SARAH E. BLOCH *is a patent agent, and* **Matthew A. Ferry** *is a partner at Morrison & Foerster LLP.*