

Genentech trade secrets theft highlights risk for biotechs

Recent high profile legal actions have drawn attention to the scale of trade secret theft in biotech. At the end of October, a federal grand jury indicted four former Genentech employees for stealing trade secrets related to the development and manufacture of biologics including Rituxan (rituximab) and Herceptin (trastuzumab) from the South San Francisco company to help a Taiwanese firm, JHL Biotech, create and sell biosimilar versions. While the recent case emphasizes that a good deal of the value created by innovator companies rests in the technical developments that get a company's products through the regulatory process, it also suggests that innovators have not been wholly effective in addressing global markets.

Despite this well-publicized case, criminal cases or indictments for trade secrets theft are uncommon, particularly in the biosciences. In 2018, the office of the US attorney general made announcements about just 17 distinct cases, four of which had bioscience connections.

Besides the Genentech case, two rice researchers from China were **charged** in August with stealing rice seeds from the Kansas facility of Aurora, Colorado-based pharming firm Ventria, while in September a scientist from a Chinese-government-supported shell pharmaceutical company called Renopharma **pleaded guilty** to stealing trade secrets from Brentford, UK-based

GlaxoSmithKline. Ventria's case started in 2017 and GlaxoSmithKline's in 2016. The fourth biotech case involved the theft of fuel enzyme technology from DuPont.

The low level of trade secret indictments, however, reflects the difficulty that governments have in prosecuting them rather than the rarity of trade secret theft. Perkins Coie, a law firm with offices across the US and in Beijing, Shanghai and Taipei, monitors filings and estimates that there are around 1,500 trade secrets cases a year, many involving bioscience firms.

"Trade secret misappropriation is a real issue for biotechnology companies," says Mark R. Wicker, a partner at Perkins Coie, especially in light of the growing trend towards developing biosimilars to treat diseases that affect large patient populations, he adds. "Many aspects of these biologics, including their manufacture, are protected as trade secrets."

Smaller biotech companies may be more prone to trade secret theft than established firms, says James Schroeder, Suzhou City, China-based US patent attorney and managing partner of Bioinnovation Legal. "While it is likely the latest case [Genentech] can protect itself well, the risks faced by the start-up world will be much higher."

Some of the manufacturing details are made public in patent disclosures, but much of the information that takes a patented biologic through the regulatory process to approval

Not 'fake' meat but 'clean'

Two US agencies agreed to share the oversight of lab-grown meat products, according to new guidelines issued by the US Food and Drug Administration and the United States Department of Agriculture in November. The decision to place the burden squarely on both agencies resulted from a joint meeting in October, after which it was agreed that the FDA will oversee cell culture (collection, banking, growth and differentiation) and the USDA, which has jurisdiction over meat and poultry, will step in for the production and labeling.

The guidance, as far as it goes, has garnered praise from cattlemen and lab-grown meat producers alike. The US Cattlemen's Association called it a "step in the right direction" while the Good Food Institute, which advocates for cell- and plant-based meat substitutes, issued an approving statement. Consensus is that the shared supervision plays to the strengths of each agency, with the FDA's expertise in cell culture technology and the USDA's in food production. Also encouraging to all was the agencies' statement that no new legislation is required.

But the nagging question is how the label should read. Missouri, with a large beef cattle industry, has already stepped into the fray and, absent federal guidance, passed its Missouri Cattleman's Fake Meat Bill, which went into effect in August 2018. The new law prohibits "misrepresenting a product as meat that is not derived from harvested production livestock or poultry" and thus bans lab-grown products from using a meat label. Producers of lab-grown meat are pushing back against the "fake meat" label, however. Several manufacturers of 'clean meat', as they prefer to call it, have filed suits to block implementation of the law based on first amendment commercial speech grounds.

This issue is urgent, as at least one company, San Francisco-based Just, was expecting to start selling cultured meat at the end of 2018.

Laura DeFrancesco

“Immuno-oncology we consider to be quite clearly the most intense area of focus across biopharma. The competition is what's breeding this level of urgency, and to a certain extent the tendency of industry to be very aggressive—at the risk of being overly aggressive.” Chris Shibutani, an analyst at Cowen in Boston, reflects on the news that combining the cancer drug epacadostat with immunotherapy failed in the clinic, causing researchers to worry that combination trials are moving too fast. (*Nature News*, 19 November 2018)

“If the consumer sees the benefit [of gene-edited foods], I think they'll embrace the products and worry less about the technology.” Dan Voytas, of the University of Minnesota and CSO of Calyxt, whose genetically edited soybeans, modified to improve health benefits, may be among the next generation of biotech foods to hit the market. (*NewsGram*, 15 November 2018)



Four former Genentech employees were indicted for trade secrets theft.