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US FTC Ruffles Pharma's Feathers Again

by Jessica Merrill

Dust has barely settled around the uncertainty stirred up by the Federal Trade Commission's view of the Amgen/Horizon merger and now the US regulator is taking another surprising action.

A cautious optimism had settled over the pharmaceutical industry's thinking on the regulatory outlook for deals after the US Federal Trade Commission reached an agreement with *Amgen, Inc.* to allow its planned merger with Horizon Therapeutics to close.

But now the agency has suddenly turned on the industry again with another surprising action, raising new questions for deal strategists. This time FTC has taken issue with a small single-asset licensing deal signed between *Sanofi* and *Maze Therapeutics* for an ultra-rare disease.

The agency announced on 11 December plans to block the licensing deal on the grounds that it would eliminate a nascent competitor poised to challenge Sanofi's monopoly in the Pompe disease market. (Also see "*FTC Suit Kills Sanofi/Maze Licensing Deal; Will It Doom The Pompe Candidate?*" - Pink Sheet, 11 Dec, 2023.)

Key Takeaways

- FTC has revealed another surprising action, raising new questions for deal strategists.
- The US agency has taken issue with a small single-asset licensing deal signed between Sanofi and Maze Therapeutics for an ultra-rare disease.
- The action is unique in the biopharma space in that it targets a smaller licensing agreement rather than an outright acquisition.

Under the agreement signed in May, Sanofi agreed to pay $150m up front for development and commercial rights to Maze's glycogen synthase 1 (GYS1) program, including MZE001, a Phase II-ready asset with the potential to be

the first oral treatment for the rare disorder. The deal was valued at $750m including milestone payments. (Also see "*Sanofi Partners With Maze On Oral Pompe Drug*" - Scrip, 1 May, 2023.)

The deal seemed like a natural fit for Sanofi, which currently dominates the treatment market for Pompe disease with a long heritage selling infused enzyme-replacement therapies to patients with the rare disease. An oral drug would be convenient for patients and help Sanofi prolong the life of its mature franchise, but from the FTC's perspective, it looked like an opportunity for Sanofi to prolong the life of its blockbuster-sized business by slowing down the development of a rival.

Targeting Licensing Deals

The FTC's move, which led Sanofi to terminate the agreement with Maze, presents yet another case for drug manufacturers to contemplate when pursuing deals. The action is unique in the biopharma space in that it targets a smaller licensing agreement rather than an outright acquisition and it also goes after a drug for an ultra-rare disease, a space that has historically been granted more leeway when it comes to regulation.

"This resets the equation a little bit because now we're talking about co-development and partnership deals and licensing deals," ZS Associates principal Cody Power said. "The idea that you can be a co-development partner and still be subject to anti-trust is not something that most of these companies really ever anticipated. Their argument before would have been transaction structure is a partial hedge."

But Powers said the FTC's action shouldn't come as a big surprise to industry players in that it echoes some recent crackdowns on dealmaking in other sectors like tech, where the agency has attempted to block some smaller-sized deals in terms of deal value.

The latest development just adds one more layer for dealmakers to navigate and may suggest increased caution for rare disease players, which haven't tended to face as much scrutiny.

EY Americas industry markets leader, health sciences and wellness Arda Ural said the outlook for pharmaceutical sector dealmaking remains encouraging with the Amgen/Horizon deal having closed, *Pfizer Inc.*'s $43bn acquisition of *Seagen Inc.* cleared to close in a couple days, and several recent deal announcements.

"We are still cautiously optimistic in regards to the macro overhangs receding and this does not change the tone," he told *Scrip*. "It does, however, add more complexity to the environment that pharma needs to do business. This regulatory uncertainty further muddies the water and only increases the unpredictable nature of target selection and deal execution."

The FTC's attempt to block Amgen's merger with Horizon was also unique in that the agency

took issue with Amgen's rebating strategy for its current portfolio and asserted the company would try to tie rebates for Horizon products to Amgen's core brands. It's not clear how the FTC's argument would have held up in court, but the two parties settled the disagreement with Amgen vowing not to include Horizon's products in rebate bundling deals. (Also see "*Amgen's FTC Settlement To Allow $27.8bn Horizon Deal Closure Sets New M&A Precedent*" - Scrip, 1 Sep, 2023.)

The cases are part of a hardline approach by the FTC under the Biden Administration. (Also see "*US FTC Removing 'Handcuffs' To Pursue Pharma Companies, PBMs For Antitrust Violations*" - Pink Sheet, 6 Jul, 2021.)

Echoes Of Roche/Spark

While it is unusual for the FTC to take issue with deals for early-stage pharmaceutical pipeline assets, it is not without precedent. In 2019, the agency delayed *Roche Holding AG*'s acquisition of the gene therapy specialist *Spark Therapeutics, Inc.* over a similar concern – that the company would delay the development of a gene therapy for hemophilia A to protect its blockbuster brand Hemlibra (emicizumab).

While the FTC ultimately approved Roche's $4.8bn acquisition of Spark, in that instance Roche did delay the development of the original gene therapy program for hemophilia A and announced the official discontinuation of the program this year. (Also see "*Roche Eyes More Growth Opportunities For Vabysmo*" - Scrip, 27 Jul, 2023.) That said, the gene therapy space has been beset by setbacks, including questions about safety, and Roche has continued to invest in the development of a gene therapy for hemophilia. It recently announced it is advancing a newer program, SPK-8011, into Phase III testing that it says could provide more durable and stable factor VIII expression for years.

With the Roche/Spark acquisition, the FTC said at the time that it allowed the deal to go through because other competitors were also developing gene therapies for hemophilia A. Indeed, *BioMarin Pharmaceutical Inc.* was further ahead in the development of a gene therapy for the blood disorder and finally launched the product, Roctavian (valoctocogene roxaparvovec), in the US earlier this year. (Also see "*Its Gene Therapy Roctavian Finally Approved With $2.9m Price, BioMarin Aims To Prove Doubters Wrong*" - Scrip, 30 Jun, 2023.)

The FTC clearly did not feel the same about the case of Sanofi and its presence in Pompe disease, where it leads the market with Nexviazyme (avalglucosidase alfa) and Myozyme (alglucosidase alfa). And drugs for ultra rare populations – which command an ultra-premium price but are complex to manufacture and distribute – tend to have long commercial lives because they don't often attract biosimilar competition. The two drugs combined generated €917m ($989.8m) in the first nine months of 2023.