

Amgen/Horizon Therapeutics' FTC suit carries implications beyond pharmaceutical mergers - advisors

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- Concern that bundling-related rebates can be a headwind in future merger reviews
- Agency victory could have “really material effect” on dealmaking, lawyer says
- Intervention raises stakes for looming decision on Pfizer’s acquisition of Seagen

The US Federal Trade Commission’s (FTC) suit to block Amgen’s [NASDAQ:AMGN] USD 27.8bn acquisition of Horizon Therapeutics [NASDAQ:HZNP] carries implications beyond pharmaceutical mergers and raises new concerns for firms that rely on cross-market bundling, according to interviews with three antitrust lawyers.

A vertical merger with no obvious overlaps, the deal announced in December of 2022 reflects the sort of transaction likely to have sailed through antitrust approval during much of the past four decades, perhaps with a structural remedy to resolve any competition concerns, the lawyers agreed.

In targeting the pharmaceutical ecosystem and its effect on drug prices, the FTC opens a new front in its war against consolidation that threatens to cast additional scrutiny on many acquirers that make use of multi-product discounts, the lawyers said.

“That approach can be not only questioned, but also could be used against you in future transactions,” said Noah Brumfield, a partner in the antitrust practice at Allen and Overy.

“It puts at risk a number of business strategies, not only in the pharma space but across other industries,” he added.

Under the administration of President Joe Biden, antitrust enforcers from the FTC – like their counterparts at the US Department of Justice – have not been shy about pushing the envelope of antitrust law in an effort to restore what they describe as broken competition across a range of sectors.

Their theory in the Amgen case is as novel as any, according to practitioners and Amgen.

In their complaint filed on 16 May in the Northern District of Illinois, enforcers say Amgen has a history of leveraging rebates or discounts on its high-volume blockbuster drugs to the disadvantage of competitors.

The Thousand Oaks, California-based pharma giant uses its market power to entice insurers and pharmacy benefit managers (PBMs) to grant Amgen drugs preferred placement on formularies – the lists of covered and available medications, the FTC alleges.

Acquiring Dublin, Ireland-based Horizon would enable Amgen to use cross-market bundling to encourage adoption of the target's two monopoly drugs, Tepezza and Krystexxa, to the exclusion of alternatives currently in the development pipeline, the plaintiff's theory goes.

Tepezza, which is used to treat thyroid eye disease, costs approximately USD 350,000 for a six-month supply; while Krystexxa, for chronic refractory gout, can cost upwards of USD 650,000 per year, the complaint states.

In its answer, Amgen notes that the FTC has never before challenged a pharmaceutical merger that did not include a product overlap or some potential competition between the parties.

Describing the FTC's theory as "novel" and "highly speculative," lawyers for the defense argued that Amgen would have neither motive nor ability to exercise market power in such a fashion.

"Amgen also made clear that it would be willing to formalize that commitment in a binding consent order," the response states.

Proving that Amgen intends to use its bundled products to suppress competing drugs and that the deal should thus be blocked will be a heavy lift for the government, the independent lawyers agreed.

"They really do need to put forward evidence to explain the 'how,' and it can't just be speculative," Brumfield said.

Revisiting the 1960s

He sees analogies with the 1960's-era case in which the FTC successfully blocked Procter and Gamble's [NYSE:PG] acquisition of Clorox [NYSE:CLX]. Though those parties were not direct competitors, the court agreed that the deal would enable the acquirer to realize efficiencies in advertising and otherwise, further entrenching its market dominance in the household products space, he said.

In addition to documents laying out the parties' rationale for the merger and the usual expert witnesses, the agency may need to produce insurers or PBMs who can testify to the likelihood of Amgen engaging in such behavior in the future, said Jeny Maier, a partner in the antitrust practice at Axinn.

A loss by the government could offer an encouraging – albeit expensive – example of merger parties successfully staring down enforcers in court to get a large deal through. A win would add significant new complication to the calculus of which deals should or can get done, she said.

"It could have a really material effect on pharmaceutical dealmaking going forward," Maier said.

"It will cause a rethink about how parties evaluate deals and what they conceive of as the benefits of a combination," she added.

Should the deal come apart, Amgen has agreed to pay a termination fee of USD 974.4m, according to documents filed with the Securities and Exchange Commission.

Private litigation weighs on FTC's thinking

The FTC's claims against Amgen mirror those in a separate private lawsuit brought by Regeneron Pharmaceuticals [NASDAQ:REGN], which has accused Amgen of an illegal bundling scheme that encourages payers to buy its cholesterol drug Repatha, in exchange for rebates on must-have drugs like arthritis treatment Otezla. Amgen's motion to dismiss that case was denied in February, as reported.

"Some of this, I believe, is colored by the private litigation; the FTC believes that it substantiates the claim that this conduct is likely to happen," said Jonathan Lewis, an antitrust partner at Lowenstein.

Given more than a year of rhetoric by the agency about the need to address the [role of PBMs](#) and other drivers of costs in the pharmaceutical space – including bundling, specifically – parties are cognizant of the elevated risk of intervention, he said.

"The landscape has changed...in terms of the timeline, in terms of the likelihood of a challenge," Lewis said.

Last week, six states joined the FTC's suit – including California, New York, Illinois, Minnesota, Washington and Wisconsin – even as Amgen's stock got a slight boost Friday amid [reports](#) of discussions to settle the litigation. Amgen has agreed to delay closing on the transaction until at least 31 October.

The Amgen suit will also undoubtedly increase anxiety around another pending pharma mega-deal, Pfizer's [NYSE:PFE] USD 43bn proposed acquisition of Seagen [NASDAQ:SGEN], which remains under review by the FTC, Axinn's Maier said.

Pfizer has not seen the same public accusations of bundling abuse, which could make it a better bellwether about enforcers' posture toward future deals in the space. "Basically, is the Amgen case an anomaly or is it predictive of a more expansive approach, going forward?" she said.

by Aldrin Brown in Los Angeles

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