4 Lessons From FTC's Successful Bid To Block Edwards Deal

By **Eric Hochstadt, Craig Falls and Tony Chan** (February 3, 2026)

Eric Hochstadt

Craig Falls

Tony Chan

The Federal Trade Commission's recent victory blocking Edwards Lifesciences Corp.'s proposed acquisition of JenaValve Technology Inc. offers lessons for parties advancing future transactions for innovators of medical devices, in the life sciences and any industry heavy in research and development, while also highlighting risks for parties negotiating mergers and acquisitions.

The case exemplifies a successful challenge of a 2 to 1 merger between competitors in an innovation market that the FTC touted as "a major victory for the Trump-Vance FTC, American patients, and U.S. healthcare innovation."[1] This article discusses four key insights for deals with startups in life sciences and beyond.

1. Pipeline-to-Pipeline Overlaps and Innovation Theory

The FTC has frequently challenged, mostly via settlements, life sciences transactions in which one party has an approved and/or commercialized product and the other party has a potentially competing product in clinical trials. The Edwards case, however, features the first successful litigated challenge to a transaction in which both parties' products — in this case, transcatheter aortic valve replacement devices to treat aortic regurgitation, or TAVR-AR — were preapproval.

In the Jan. 28 decision in FTC v. Edwards Lifesciences Corp., the U.S. District Court for the District of Columbia acknowledged the novelty of such a challenge yet found support for blocking the transaction under sections of the 2023 U.S. Department of Justice and FTC merger guidelines and portions of the U.S. Court of Appeals for the Fifth Circuit's 2023 decision in Illumina Inc. v. FTC, which addressed a vertical combination rather than the horizontal overlap present in Edwards.[2]

Importantly, rather than analyze the transaction under a potential competition theory, which would have required the FTC to show a reasonable probability of entry for both parties' products, the court ruled that the combination reduced current competition in efforts to research, develop and commercialize TAVR-AR.

The court cited competition between the parties on nonprice dimensions of speed to market, clinical testing, expanding valve size and greater patient indications. It also considered modest early price competition to costs recovered from hospitals participating in clinical trials.

2. Pipeline-to-Pipeline Combinations and Competition

The court in Edwards recognized that "not all mergers that eliminate competition decrease firms' incentives to innovate" and refused to grant the FTC a presumption of illegality based on the FTC's market concentration metrics, which focused on shares of clinical trial

sites— because of the lack of revenues.[3]

The court's decision to enjoin the transaction was nonetheless driven by market structure as the court found that the parties were the only competitors in the relevant market, no other (foreign) TAVR-AR products were on the path to approval before 2034, and Edwards would thus have a monopoly for a significant period.

The court was also influenced by evidence that current clinical-stage competition between the parties on nonprice dimensions "incentivized them to make decisions that have benefited and will continue [if the transaction is blocked] to benefit patients and physicians."[4]

In the merger-to-monopoly context, the court rejected the defendants' arguments that Edwards would continue to innovate postmerger because its biggest competitor was the disease itself. The court explained that, while the desire to compete against the disease might cause Edwards to innovate a single product, Edwards was likely to abandon one of the two products and would lose the incentives to improve quality and pricing that exist when there is a significant second competitor.[5]

The Edwards case preserves the ability of transacting parties to argue that this decision is unique to merger-to-monopoly scenarios and that combined ownership of developmental products will not decrease incentives to innovate so long as there is at least one other significant innovator making progress toward approvals. Indeed, the aggressive competition that the court found in the TAVR-AR market existed with only two competitors.

In addition to showing lack of diminished innovation incentives, it would help the parties to show countervailing efficiencies that would accelerate development, lower costs, or improve the efficacy or safety of the products. The parties in Edwards argued for such efficiencies, yet the court found that they failed to calculate or verify the benefits to the satisfaction of the court.[6]

3. Short Shrift for "Weakened Competitor" Defenses

The Edwards defendants argued that JenaValve's competitive significance should be discounted because (1) JenaValve received a Food and Drug Administration deficiency letter on its application for premarket approval and (2) the company lacked manufacturing capacity and financial resources to support a commercial launch.

Such circumstances are common in life sciences and other innovation industries in which startup companies often have resources to develop a product yet are unable to transition successfully on their own to the commercialization stage.

That reality often serves as a legitimate business reason for alliances with larger or more experienced commercial partners. The court acknowledged these limitations yet held that even if JenaValve would have struggled to develop its TAVR-AR device independently, JenaValve could merge with another medical device buyer who lacks a competitive overlap or obtain private financing through a Series D investment round.

This analysis reveals an antitrust policy dilemma. For startups that find themselves in similar circumstances to JenaValve, should antitrust law enable acquisition by direct competitors simply because of commercialization challenges?

Alternatively, would a contrary rule that takes too rosy a view of prospects for alternative

financing result in startups failing to launch? How JenaValve performs postabandonment by the Edwards deal could be influential to future courts.

4. Clear Skies and Sell-Side Diligence

Note that Edwards itself shifted the antitrust risk profile of this deal via a late-breaking acquisition that immediately predated the agreement with JenaValve. Indeed, Edwards was not a competitor of JenaValve when the parties began negotiating their agreement and became a competitor just one day before, according to the court, secretly acquiring JenaValve's competitor JC Medical Inc.

The court explained that "JenaValve's CEO was totally blindsided by the news" and complained that he "would not have agreed to a deal with Edwards" if he had known about the antitrust overlap. Indeed, the FTC's opening statement featured an email from the JenaValve CEO stating that "this is not the transaction we signed on for: we would have negotiated different transaction terms (breakup fee, IP, divestiture) but more than likely no deal."[7]

The Edwards case thus highlights a risk sellers face when considering transactions that initially appear to have low antitrust risk. Compared to higher-risk deals, the seller may not be positioned to insist that the buyer accept divestiture or other hell-or-high-water obligations that would provide the seller deal certainty.

Yet, in low-risk deals, sellers frequently insist on a clear skies provision that prevents the buyer from making subsequent acquisitions between signing and closing that could materially alter the antitrust risk.

Clear skies provisions, however, typically restrict the buyer from the date of signing. Absent the seller or its counsel insisting on a presign representation, the buyer could inject risk on its own by creating a direct overlap prior to signing.

Thus, when diligence reveals no direct or potential future competition, sellers should consider seeking buyer representations of no change in competition risk due to an overlap as of the time of signing.

Eric Hochstadt is a partner and head of antitrust litigation at Orrick Herrington & Sutcliffe LLP.

Craig Falls is a partner at the firm.

Tony Chan is a partner and global co-leader of the life sciences and healthtech sector at the firm.

[1] https://www.ftc.gov/news-events/news/press-releases/2026/01/statement-ftc-victory-halting-anticompetitive-medical-device-deal.

[2] Case 1:25-cv-02569-RC,

[3] Slip op. at 42, 50-52.

[4] Slip op at 66.

[5] Slip op. at 67-68.

[6] See Slip op. at 88-90.

[7] https://www.ftc.gov/system/files/ftc_gov/pdf/EdwardsLifesciences-FTCOpeningStatement.pdf.