IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, *Plaintiff*, v. EDWARDS LIFESCIENCES CORPORATION, and JENAVALVE TECHNOLOGY, INC., *Defendants*.	Civil Action No.: 1:25-cv-02569-RC

JOINT STATUS REPORT

The parties submit this Joint Status Report to request the Court schedule the evidentiary hearing in this preliminary injunction proceeding. The parties are currently negotiating a Case Management and Scheduling Order ("CMSO") and believe that the Court's selection of a hearing start date will allow them to resolve outstanding issues and otherwise narrow the scope of any CMSO-related disputes they may need to ask the Court to decide. The parties agree to confer and submit a proposed CMSO, including identifying any remaining disputes, no later than seven (7) calendar days after the Court issues an order scheduling the evidentiary hearing.

On August 7, 2025, the Court entered the parties' stipulated Temporary Restraining Order ("TRO"), which expires on January 9, 2026. (Dkt. 8.) The parties agree that each side will require no more than 20 hours for testimony[1], and on that basis propose the following:

(1) Plaintiff Federal Trade Commission ("FTC") requests that the hearing begin on December 10, 2025.

(2) Defendants Edwards Lifesciences Corporation ("Edwards") and JenaValve Technology, Inc. ("JenaValve" and, with Edwards, "Defendants") request that the hearing begin on November 17, 2025.

Each side provides a short position statement below.

I. Plaintiff's Position

This case concerns Edwards' proposed acquisition of JenaValve, a $945 million deal that would combine the only two companies conducting clinical trials for transcatheter aortic valve replacement ("TAVR") devices specifically designed to treat a potentially fatal heart condition called aortic regurgitation ("AR"). Given the proposed acquisition would eliminate Defendants' current close, head-to-head competition in the TAVR-AR device market, Plaintiff is challenging it in an administrative proceeding under Sections 7 and 11 of the Clayton Act, 15 U.S.C. §§ 18, 21, and Section 5 of the FTC Act, 15 U.S.C. § 45. Plaintiff filed this preliminary injunction lawsuit under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to temporarily halt the acquisition and allow sufficient time for the full merits proceeding, which is set to begin on January 7, 2025.

[1] Plaintiff believes the 20 hours of time per side should exclude both opening statements and closing arguments. Defendants believe the 20 hours of time per side should include opening statements but exclude closing arguments.

Plaintiff requests this Court schedule the evidentiary hearing to begin on December 10, 2025. Starting that date means the hearing likely concludes around December 17, giving the Court several weeks to rule prior to the January 9 expiration of the TRO. Additionally, December 10 is about 16 weeks from today, in which time the parties need to: (1) conduct discovery, including obtaining documents from Defendants and third parties,[2] deposing witnesses, exchanging expert reports, and resolving discovery disputes; (2) file preliminary injunction briefing; (3) submit other pre-hearing filings; and (4) prepare for the hearing. To allow adequate time and reduce unnecessary burdens on the Court and the parties, Plaintiff proposed the CMSO include reasonable constraints on discovery, such as prohibiting informal letters of support[3] and limits on discovery requests, third-party subpoenas, experts, and hearing witnesses.

Defendants' proposed date of November 17, 2025 is unworkable because it is only 12.5 weeks from today—three-and-a-half weeks (or about 20%) shorter than Plaintiff's proposal. Under Defendants' proposal, the parties need to complete fact discovery by the end of September (less than six weeks from today), even though Defendants only yesterday filed their Answers in the merits proceeding and neither side has exchanged initial disclosures or issued discovery requests. Should the case proceed on Defendants' compressed timeline, Plaintiff believes even

[2] Plaintiff expects to substantially complete production of its investigative file this week.

[3] For example, Edwards—as a leading structural heart company—has financial and professional relationships with a host of medical professionals called Key Opinion Leaders ("KOLs"). Defendants may seek to deploy these numerous KOLs in various ways, including via informal letters of support, forcing Plaintiff to subpoena and depose them all—an unnecessary burden when a smaller set of formal statements under oath would do.

stricter limits on discovery would be necessary—including further capping subpoenas and discovery requests and imposing page limits on expert reports.[4]

Such reasonable limits on discovery are also appropriate given that Section 13(b) only requires the Court to decide whether "a preliminary injunction . . . would be in the public interest—as determined by a weighing of the equities and a consideration of the Commission's likelihood of success on the merits." *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001). Courts thus recognize that they are "not [being] asked to make a final determination on whether the proposed merger violates Section 7, but rather to make only a preliminary assessment of the merger's impact on competition." *FTC v. Kroger Co.*, 2024 WL 5053016, at *1 (D. Or. Dec. 10, 2024). Defendants ask the Court to hold Plaintiff to a higher standard because they may abandon the acquisition if the Court preliminarily enjoins it. But how Defendants might respond is irrelevant because, "even accepting [their] assertion that they would abandon the merger following issuance of the injunction, the result—that the public would be denied the procompetitive advantages of the merger—would be [their] doing." *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 353 (3rd Cir. 2016). Under the Section 13(b) standard, limiting discovery would appropriately focus this litigation on the key issues relevant to this Court's "preliminary assessment."

Defendants' only justification for their proposed hearing date is to claim the 3.5-week difference should be reserved for post-hearing filings and the Court's decision. Plaintiff believes

[4] The Court should not be concerned that such limits could cause undue prejudice. The underlying administrative action permits broad discovery, additional witnesses, and voluminous evidence at a hearing with a robust 210-hour time limit. *See generally* 16 C.F.R. §§ 3.1-3.83.

its proposal would better allocate the available time and, if there is not enough time for the Court to issue a written decision, it could issue an indicative ruling before the TRO expires with a written decision to follow. Moreover, instead of depriving the parties of valuable time to prepare their cases, Defendants could agree to extend the TRO by a few weeks—a reasonable solution that is within Defendants' control.[5]

Defendants assert they cannot agree to extend the TRO for business reasons and accuse Plaintiff of "procedural delays" to "increase[] the likelihood this transaction will not close." But Defendants offer no support for their claim that a December hearing would "effectively kill the transaction" and, regardless, it was Defendants who delayed the initiation of this case by months. Plaintiff issued a "Second Request" for documents in the pre-Complaint investigation on October 10, 2024. Defendants agree that nothing prevented them from substantially complying with the Second Request as early as March 17, 2025. Instead, Edwards waited nearly seven months after the Second Request was issued to substantially comply, producing documents between May 9 and May 23. Edwards' substantive engagement with Plaintiff regarding the Second Request effectively ended February 2025 and did not resume for over 3 months, when Edwards began producing documents on May 9, 2025. Despite Edwards' delays, Plaintiff acted promptly and initiated this litigation in roughly two months following Edwards' substantial compliance. Defendants controlled the timing in the pre-Complaint investigation and should not be heard to complain about a timing issue they created.

[5] The Merger Agreement sets the acquisition's closing date as January 23, 2026, but contains no restriction on Defendants extending that date.

II. Defendants' Position

Thousands of patients suffering from aortic regurgitation, a deadly, underdiagnosed, and undertreated heart valve condition, currently lack access to a potentially lifesaving treatment in advanced development. Edwards' acquisition of JenaValve offers the best chance to make this treatment widely available to patients more quickly and effectively than the financially and operationally challenged JenaValve could on its own. Far from advancing consumer welfare, the FTC's merger challenge, if successful, will stifle competition, slow innovation, and delay or potentially prevent critical medical advancements from reaching thousands of patients.

Defendants respectfully request a preliminary injunction hearing beginning on November 17, 2025.[6] This schedule properly balances the need for tailored fact and expert discovery, while ensuring the Court has sufficient time to evaluate the evidence in a five- to seven-day hearing, review post-hearing briefing, and rule before the stipulated TRO expires on January 9, 2026. Speedy timing is the norm for these types of cases. *See, e.g.*, *United States v. Booz Allen Hamilton*, 2022 WL 9976035 (D. Md. 2022) (78 days from complaint to hearing). Notwithstanding the FTC's yearlong pre-complaint investigation and corresponding discovery advantage, Defendants are willing to streamline discovery to provide more time for the Court to evaluate the merits and reach a timely decision.

Defendants announced the transaction on July 24, 2024, and the FTC issued its "Second Request" on October 10, 2024. Since then, Defendants agreed to extend the FTC's time to investigate by several months, produced over a million pages of documents from nearly 50

[6] If the Court's schedule does not permit this proposal, Defendants request an earlier hearing subject to the Court's availability.

custodians, and provided ten current and former employees for dozens of hours of sworn testimony. The FTC has also taken one-sided nonparty discovery to which Defendants still lack complete access. Accordingly, the FTC's request for additional time seems not driven by a need for more discovery, but because further procedural delay increases the likelihood this transaction will not close. The FTC's proposed schedule would compress the Court's timeline for considering the evidence, heighten instability at JenaValve, and effectively kill the transaction by running out the clock, regardless of whether the FTC can meet its burden**.**

Under the FTC's unrealistic proposal, post-hearing briefing—which the parties agree should be 100 pages per side)—would be submitted to the Court no earlier than January 2, 2026, leaving the Court only a week to issue an opinion before the TRO expires on January 9, 2026. To solve this problem of its own creation, the FTC asks Defendants to renegotiate either the stipulated TRO or the merger agreement's expiration date of January 23, 2026. However, these dates were carefully negotiated to avoid the instability JenaValve would face with additional delay, and to allow time to secure financing and complete the transaction. The closing date is "quite clearly a core term of the acquisition," and, because "the FTC nowhere places a deadline upon itself by which to conclude its inquiries," Defendants' and patients' interests in quickly resolving this action and closing the acquisition should not "be so lightly forfeited to the vagaries of an administrative timeline." *FTC v. Tempur Sealy*, 768 F. Supp. 3d 787, 861-62 (S.D. Tex. 2025). The government's "*just-close-later* position" has no limiting principle, and its attempt to extract a later TRO date as a remedy for foisting an unworkable schedule upon the Court—especially over the winter holidays—is misguided. *See id.*

Alternatively, the FTC suggests the Court should only accept Defendants' proposed date if it lowers the substantial burden the government carries to secure a preliminary injunction, effectively granting a preliminary injunction as a matter of course and deferring any meaningful consideration of the merits to a multi-year administrative process. As the Supreme Court recently observed, however, a "preliminary injunction is an extraordinary equitable remedy that is never awarded as of right." *Starbucks Corp. v McKinney*, 602 U.S. 339, 345–46 (2024). As courts routinely recognize, preliminarily enjoining a merger is "an extraordinary and drastic remedy" because the FTC's lengthy administrative process exceeds the "short life span" of most transactions. *FTC v. Microsoft Corp.*, 681 F. Supp. 3d 1069, 1084 (N.D. Cal. Jul. 10, 2023) (quoting *FTC v. Exxon Corp.*, 636 F.2d 1336, 1343 (D.C. Cir. 1980)). "No substantial business transaction could ever survive the glacial pace of an FTC administrative proceeding." *Foster*, 2007 WL 1793441, at *51. The Court's role is crucial here. If "Congress did not want federal courts to play some meaningful role in the injunction process, it could have given injunctive power directly to the FTC. Congress did not structure the process that way." *FTC v. Foster*, 2007 WL 1793441, at *51 (D.N.M. May 29, 2007).

Even FTC staff and Commissioners recently agreed that a "federal court preliminary injunction almost always obviates the need for further administrative proceedings." *In the Matter of Tempur Sealy Int'l. and Mattress Firm Group*, 2024 WL 4544179, at *1 (F.T.C. Oct. 15, 2024); *see In the Matter of Synopsys, Inc./Ansys, Inc.*, Matter No. 2410059, Statement of Chairman Andrew N. Ferguson at 3 n.7 ("For nearly all of the Commission's merger-enforcement actions, however, the preliminary-injunction litigation and subsequent appeal are dispositive."). "In fact, when the FTC prevails in a preliminary injunction hearing, merging parties have proceeded with

the administrative hearing on only a few occasions because the proposed mergers almost always fall apart. It has also been more than 30 years since the Commission proceeded—after losing a preliminary injunction—to block a merger through an administrative proceeding." Dissenting Statement of Commissioner Melissa Holyoak Joined by [now-Chairman] Andrew N. Ferguson, *In the Matter of The Kroger Company and Albertsons Companies*, Docket No. 9428, Motion for Continuance of Evidentiary Hearing (May 29, 2024) (citing cases).

Defendants cannot agree to further delay and must prioritize their obligations to shareholders and employees—and, more importantly, the patients who stand to benefit from the timely, widespread introduction of innovative and lifesaving technology. Accordingly, Defendants respectfully request that the Court order the hearing to start on November 17.

Dated: August 19, 2025

Respectfully submitted,

/s/ Laura R. Hall

Laura R. Hall (N.Y. 4337408)
Barrett J. Anderson (D.C. Bar 1024159)
Lisa De Marchi Sleigh (D.C. 485853)
Jay Tymkovich (D.C. 241366)
Hilla Shimshoni (D.C. 1033015)
Federal Trade Commission
Bureau of Competition
400 Seventh Street, S.W.
Washington, D.C. 20024
Telephone: (202) 326-3282
Email: lhall1@ftc.gov

Counsel for Plaintiff
Federal Trade Commission

/s/ Joshua Lipton
Joshua Lipton (D.C. Bar No. 461731)
Michael J. Perry (*pro hac vice* pending)
Jamie E. France (*pro hac vice* pending)
Stephanie Pearl (*pro hac vice* pending)
Logan Billman (*pro hac vice* pending)
Connor Leydecker (*pro hac vice* pending)
GIBSON, DUNN & CRUTCHER LLP
1700 M Street, NW
Washington, DC 20036
Telephone: (202) 955-8226
Email: jlipton@gibsondunn.com
Email: mjperry@gibsondunn.com
Email: jfrance@gibsondunn.com
Email: spearl@gibsondunn.com
Email: lbillman@gibsondunn.com
Email: cleydecker@gibsondunn.com

D. Bruce Hoffman (D.C. Bar No. 495385)
Ryan A. Shores (D.C. Bar No. 500031)
Jeremy J. Calsyn (D.C. Bar No. 467737)
Jacob M. Coate (*pro hac vice* pending)
Kelton Anderson (*pro hac vice* pending)
CLEARY GOTTLIEB STEEN & HAMILTON LLP
2112 Pennsylvania Ave., N.W.
Washington, D.C. 20037
Telephone: (202) 974-1500
Email: rshores@cgsh.com
Email: bhoffman@cgsh.com
Email: jcalsyn@cgsh.com
Email: jcoate@cgsh.com
Email: keanderson@cgsh.com

Counsel for Defendant
Edwards Lifesciences Corporation

/s/ Jonathan Klarfeld
Jonathan Klarfeld (D.C. Bar No. 1025315)
Michael S. McFalls (*pro hac vice* pending)
Samer M. Musallam (*pro hac vice* pending)
Elizabeth McInerney (*pro hac vice* pending)
ROPES & GRAY LLP
2099 Pennsylvania Ave., N.W.
Washington, D.C. 20006
Telephone: (202) 508-4600
Email: Jonathan.Klarfeld@ropesgray.com
Email: Michael.McFalls@ropesgray.com
Email: Samer.Musallam@ropesgray.com
Email: Elizabeth.McInerney@ropesgray.com

Matthew L. McGinnis (*pro hac vice* pending)
ROPES & GRAY LLP
800 Boylston Street
Boston, MA 02199-3600
Telephone: (617) 951-7000
Email: Matthew.McGinnis@ropesgray.com

Counsel for Defendant
JenaValve Technology, Inc.