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 **PUBLIC VERSION**

PLAINTIFF'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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GLOSSARY OF ABBERVIATED OR DEFINED TERMS

1. Exhibits and Transcripts

DX	Defendants' Exhibit
PDX	Plaintiff's Demonstrative
PX	Plaintiff's Exhibit

2. Documents and Filings

Edwards Answer	Defendant Edwards Lifesciences' Answer to Complaint for Preliminary Injunction (August 29, 2025) (Dkt. No. 49)
JenaValve Answer	Defendant JenaValve Technology's Answer to Complaint for Preliminary Injunction (August 29, 2025) (Dkt. No. 53)
Merger Guidelines	U.S. Department of Justice and Federal Trade Commission Merger Guidelines (Dec. 18, 2023)

3. Glossary of Terms

Term	Definition
ALIGN-AR	JenaValve's TAVR-AR pivotal trial
AR	Aortic regurgitation
ARTIST	JenaValve clinical trial comparing Trilogy to SAVR in patients at low to intermediate risk to SAVR
AS	Aortic stenosis
CAP	FDA's Continued Access Protocol
Edwards	Edwards Lifesciences, Corp.
EFS	Early Feasibility Study
FDA	U.S. Food & Drug Administration
IDE	FDA's Investigational Device Exemption
HMT	Hypothetical Monopolist Test
HSR	Hart-Scott-Rodino Premerger Notification
J-Valve	Edwards' TAVR-AR device rebranded as SOJOURN

Term	Definition
JenaVAD	JenaValve's LVAD Registry
JenaValve	JenaValve Technology, Inc.
JC Medical	JC Medical, Inc.
JCM	JC Medical
JOURNEY	Edwards' TAVR-AR pivotal trial
LVAD	Left Ventricle Assisted Device
PMA	Premarket Approval
Proposed Transaction	Proposed acquisition of JenaValve by Edwards
Relevant Geographic Market	United States
Relevant Product Market	TAVR-AR devices
SAPIEN	Edwards' TAVR-AS device
SAVR	Surgical Aortic Valve Replacement
SOJOURN	J-Valve
ssAR	Severe, symptomatic aortic regurgitation
TAVR	Transcatheter Aortic Valve Replacement
Trilogy	JenaValve's TAVR-AR device

4. Live Hearing Witnesses

Witness Name	Company / Affiliation	Title
Bernard Zovighian	Edwards Lifesciences	Chief Executive Officer
Blessie Concepcion	Edwards Lifesciences	Vice President of Clinical Affairs
Daniel Sun	JenaValve Technology	Senior Director of Global Marketing
Dennis McWilliams	Sante Ventures	Defendants' Venture Capitalist Expert
Donald Bobo	Edwards Lifesciences	Corporate Vice President, Strategy & Corporate Development

Witness Name	Company / Affiliation	Title
Dr. Aaron S. Kesselheim	Harvard Medical School, Brigham and Women's Hospital	Plaintiff's FDA Regulatory Expert
Dr. Duane Pinto	JenaValve Technology	Chief Medical Officer
Dr. Elizabeth Bailey	Charles River Associates	Defendants' Economic Expert
Dr. Mark Turco	JC Medical	Former President and CEO
Dr. Nathan E. Wilson	Econic Partners	Plaintiff's Economic Expert
Dr. Stanley Joseph Chetcuti	University of Michigan Health	Physician; Clinical Professor of Internal and Cardiovascular Medicine
Dr. Torsten Vahl	Columbia University Medical Center	Physician; Assistant Professor of Medicine
Greg Larkin	Medtronic	Vice President, Business Development and Strategy
Jan Keltjens	JenaValve Technology	Chairman of the Board
Jeremy Bierman	Edwards Lifesciences	Vice President of Strategy & Analytics
John Kilcoyne	JenaValve Technology	Chief Executive Officer
Laksen Sirimanne	Edwards Lifesciences	Senior Vice President of Research & Development, TAVR and Surgical Structural Heart
Larry Wood	Edwards Lifesciences	Former Corporate Vice President and Group President of TAVR and Surgical Structural Heart
Pooja Sharma Rao	Edwards Lifesciences	Senior Vice President of Marketing, Strategy, and Project Management

5. Designation Witnesses (Including Video and Non-Video Designations)

Witness Name	Company / Affiliation	Title
Andrew Hack	Bain Capital Life Sciences	Partner at Bain Capital, JenaValve Board Member
Andrew Walls	Edwards Lifesciences	Vice President of GSC Integrations
Courtney Darby	JenaValve Technology	Head of Global Health Economics, Market Access, and Reimbursement
Dan Dearen	JenaValve Technology	Board Member
Daniel Lippis	Edwards Lifesciences	Corporate Vice President and Group President of TAVR and Surgical Structural Heart
Devin Baerenwald	JenaValve Technology	Director of Final Clinical and Training
Dr. Dean Kereiakes	Christ Hospital	Physician; Chairman of the Heart & Vascular Institute
Dr. James McCabe	Beth Israel Deaconess Medical Center	Physician; Head of Structural Heart Therapies
Dr. Vinod Thourani	Piedmont Healthcare	Physician; Chairman of the Department of Cardiovascular Surgery
Gilbert Madrid	Laguna Tech USA	Chief Executive Officer
Irma Darmali	Edwards Lifesciences	Director of Corporate Development
Justin Castelli	Boston Scientific	Vice President, New Business Development
Peter Spadaro	JenaValve Technology	Chief Commercial Officer

Witness Name	Company / Affiliation	Title
Scott Ullem	Edwards Lifesciences	Chief Financial Officer
Steve Sloan	JenaValve Technology	Vice President of Finance

INTRODUCTION

Edwards, operating in secrecy, designed the proposed acquisition of JenaValve (the "Proposed Transaction") and the consummated acquisition of JC Medical to stifle competition and subvert the antitrust laws. Edwards concealed the JC Medical deal from JenaValve—conduct JenaValve described as fraud[1]—and structured it to dodge HSR review.[2] These actions were glaringly anticompetitive; as JenaValve employees immediately grasped, "Edwards just bought the AR market,"[3] and would likely "see which [device] is better and kill the other."[4]

The FTC at trial proved that the Proposed Transaction violates Section 7 several times over: (1) it tends to create a monopoly—an independently sufficient statutory basis to enjoin the transaction;[5] (2) it results in market shares and concentrations that are presumptively unlawful;[6] and (3) it eliminates substantial head-to-head competition between Defendants.[7] Each legal ground flows from a fundamental congressional judgment that competition, not monopoly, is the American way of driving medical innovation, efficacy, and output for the hundreds of thousands of Americans suffering from severe, symptomatic aortic regurgitation.

Evidence presented by the FTC in this matter demonstrated: (1) the existence of a TAVR-AR device market in the United States; (2) the U.S. TAVR-AR device market is comprised of only two firms, Edwards and JenaValve; (3) Defendants compete head-to-head to provide the highest quality TAVR-AR devices; and (4) entry by other companies is speculative, unlikely, and would result in far less competitive pressure on Edwards and JenaValve than they currently have

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[1] *See infra* § III; Kilcoyne Day 1-PM 38:14-39:13 (referencing PX2373-001); PX2162-001.
[2] *See infra* § XIII.E.
[3] PX2052-002; Sun Day 3-PM 59:12-15 (referencing PX2052-002).
[4] PX2062-002; *see also* Sun Day 3-PM 61:22-62:4 (referencing PX2062-002).
[5] *See infra* § VIII.
[6] *See infra* § IX.
[7] *See infra* § X.

on each other. Conversely, Defendants failed to rebut the FTC's case or establish that any equities, efficiencies, or procompetitive benefits would flow from the Proposed Transaction. Accordingly, the Court should preliminarily enjoin this merger so the FTC can prove its illegality in the administrative proceeding scheduled to begin on April 8, 2026.

***

The FTC showed that U.S. TAVR-AR devices is the relevant "line of commerce," 15 U.S.C. § 18, to analyze the Proposed Transaction, as confirmed by both the *Brown Shoe* practical indicia and the Hypothetical Monopolist Test.[8] Defendants claim that the U.S. TAVR-AR device market does not yet exist because JenaValve and Edwards have not yet obtained PMA approval from the FDA, but the plain text of the Clayton Act bars mergers that substantially lessen competition or tend to create a monopoly "in any line of commerce and in any activity affecting commerce."[9] Right now, Edwards and JenaValve are charging hospitals tens of thousands of dollars for each TAVR-AR valve used in clinical trials.[10] Both are spending tens of millions of dollars to develop medical devices with the expectation of receiving a return on that investment. This is, at a minimum, "activity affecting commerce." Moreover, no caselaw supports Defendants' suggestion that the antitrust laws somehow do not apply to medical device products before they receive PMA approval. To the contrary, the Fifth Circuit has recognized that a relevant market can include both products in clinical trials and products that are commercialized. *Illumina, Inc. v. FTC*, 88 F.4th 1036, 1049-50 (5th Cir. 2023).

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[8] *See infra* § VII.

[9] Defendants' theory that there are separate "innovation," "pre-market," and "commercial" TAVR-AR markets is also disconnected from the facts and law. To be sure, Defendants vie to innovate and attract premium clinical trial sites, but those are examples of competition *within* the TAVR-AR device market, not separate markets. Defendants, not the FTC, are attempting to gerrymander a market that suits their theory.

[10] *See infra* § VII.C.4.

The evidence shows that robust head-to-head competition in the TAVR-AR device market is occurring between Defendants in FDA-approved clinical trials.[11] For example, JenaValve launched the ARTIST trial before obtaining PMA approval to keep ahead of J-Valve.[12] And, after obtaining PMA approval, JenaValve plans to compete with Edwards at J-Valve clinical trial sites, including by offering rebates and other incentives.[13] Even Defendants' expert, Dr. Elizabeth Bailey, agrees that "a firm does not need to enter into commercialized TAVR-AR device sales in order to be capable of providing competitive pressure."[14] As they must, Defendants concede that only Trilogy and J-Valve have received an IDE, which allows them to be used in U.S. clinical trials, and every TAVR-AR device purchased by a U.S. hospital and implanted in a U.S. patient has been manufactured by Edwards/JC Medical or JenaValve.[15] Defendants' ordinary-course documents project a TAVR-AR device market consisting solely of Edwards and JenaValve for at least a decade.[16]

Competition between Defendants has benefited, and will continue to benefit, U.S. doctors and patients. The Court heard from JenaValve executives about their plans to accelerate the ARTIST trial and Trilogy XL valve project to stay ahead of Edwards.[17] These projects will bring Trilogy to thousands more patients, but Edwards plans to slow or stop them if the merger is completed.[18] Defendants also compete for top clinical trial sites, including by offering free or reduced-price valves to cash-strapped hospitals.[19] And the Court heard how, if the Proposed

[11] *See infra* § X.
[12] *See infra* § X.C.2.
[13] PX2414-002.
[14] DX0289 Bailey ¶ 55.
[15] *See infra* § VIII.B; Kilcoyne Day 1-PM 18:7-15.
[16] *See infra* § VIII.B.
[17] *See infra* § X.C.
[18] *See infra* § X.D.
[19] *See infra* § X.C.6; Kereiakes Dep. 33:11-34:1, 48:6-17.

Transaction is blocked, Edwards plans to accelerate its J-Valve program to compete with JenaValve.[20] The benefits of that competition would evaporate if the merger closes because, as Defendants' expert Dennis McWilliams conceded, "the only competitive pressure for JenaValve would be Edwards and JC Medical."[21] Not only would Trilogy and J-Valve cease competing, but Edwards would be powerfully incentivized to pick one device to be its second-generation AR valve and discontinue the other, as the record reflects and as Edwards has done before in the TAVR-AS device market.[22]

The FTC also showed that the relevant market has high barriers to entry due to stringent FDA regulations. Through both Dr. Aaron Kesselheim's expert testimony and the testimony of lay witnesses, the FTC established that obtaining PMA approval almost always requires conducting the full slate of clinical trials in the United States, even if the device is approved in other jurisdictions.[23] [redacted].[24] As Dr. Kesselheim explained (and Dr. Bailey and Dr. Chetcuti agreed), on average, it takes 8.5 years for a complex medical device to complete the journey from EFS to PMA approval.[25] Therefore, even if a firm attempted to enter the U.S. TAVR-AR device market tomorrow, it would start at least five years behind the market leaders, [redacted].[26] And, as multiple witnesses testified,

[20] *See infra* § X.C.3; Zovighian Day 2-PM 45:2-46:6; Bierman Day 3-AM 86:23-87:8.
[21] McWilliams Day 6-AM 108:1-16.
[22] *See infra* § X.D.3.
[23] *See infra* §§ V, XI.A; Kesselheim Day 4-PM 12:24-13:7.
[24] *See infra* §§ V, XI.A; *see also* Keltjens Day 5-PM 32:7-16.
[25] *See infra* §§ V, XI.A; Chetcuti Day 6-AM 41:23-42:3.
[26] *See infra* §§ V, XI.A.

the clinical data associated with foreign devices, particularly from China, is viewed skeptically by the FDA and frequently fails to meet the FDA's regulatory standards.[27]

Unable to meaningfully contest the antitrust merits of the FTC's case, Defendants press unquantifiable and unverifiable "public interest" arguments. As a threshold matter, it is Defendants' burden to demonstrate that these defenses rebut the FTC's prima facie case.[28] Defendants' claims about the purported benefits of the Proposed Transaction are internally contradictory and unmoored from the evidence presented to the Court:[29]

Output: Edwards claims that it will expand Trilogy output. Yet, Edwards did not produce a single ordinary course business [redacted].[30] Nor does Edwards plan to move [redacted] JenaValve's current manufacturing facilities.[31] With no plans or capabilities to produce more Trilogy valves, Edwards' greater presence at TAVR clinics will have no effect on the number of patients treated. These basic facts undermine any argument from Defendants that the Proposed Transaction will save more lives than if the transaction is enjoined.

Alleged entry: Edwards theorizes that "fast followers" are waiting in the wings to enter the U.S. TAVR-AR market after Edwards sent a "massive signal" that the market is worth investment.[32] But there is no prospect of a "fast follower" because any prospective entrant would be at least five years behind Defendants. Moreover, any signal was sent nearly 18 months ago

[27] Zovighian Day 2-PM 72:13-18; Bobo Day 2-PM 128:15-129:8; *See infra* §§ V, XI.A.
[28] *See infra* § XI; *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990).
[29] Defendants' arguments are further undermined by their witnesses' lack of credibility. Defendants' witnesses repeatedly made representations to the Court that were contradicted by documents or prior testimony.
[30] *See infra* § XI.D. Bobo Day 2-PM 147:10-148:25 (referencing PDX 006).
[31] *See infra* § XI.D. Bobo Day 3-AM 25:4-26:9.
[32] Day 1-AM 56:13 (EW Opening Arg.).

when Edwards acquired JC Medical and signed the JenaValve merger agreement. In that time, no other company has entered the market or even announced plans to begin U.S. clinical trials. Ordinary-course documents confirm that foreign TAVR-AR companies place no competitive pressure on Defendants,[33] while the record is replete with evidence showing Defendants responding to each other to innovate, move faster, and develop the U.S. TAVR-AR market.[34]

JenaValve alternative buyers: In significant tension with their "fast follower" argument, Defendants assert that no other company would be interested in JenaValve if it becomes available again. [redacted].[35] [redacted].[36] Other large companies with TAVR programs, like Abbott or Boston Scientific, also could be potential acquirors of JenaValve, especially if the company ever were willing to accept a reduced purchase price. Thus, the but-for world if the transaction is enjoined likely is not a standalone JenaValve, but a JenaValve acquired by an Edwards competitor.

Standalone JenaValve: Though Defendants disclaim any failing or flailing firm defense to avoid the attendant legal requirements,[37] they nonetheless paint JenaValve as a firm incapable of standing on its own two feet. Setting aside the likelihood of another acquiror, a standalone JenaValve is likely to succeed at commercializing Trilogy. First, JenaValve is run by medical technology veterans with experience developing, financing, and selling, medical device

[33] *See infra* §§ VIII.B, XI.
[34] *See infra* § X.
[35] *See infra* § XI.B.2; Larkin Day 2-AM 142:5-8.
[36] *See infra* § XI.B.2; Larkin Day 2-AM 134:23-135:11, 138:19-139:21.
[37] *See infra* § XI.B. The Court should reject Defendants' invitation to accept a legally insufficient efficiencies defense in the guise of "equities."

companies.[38] Second, JenaValve's cash reserves will be bolstered by the $45 million merger breakup fee[39] and any recovery on fraud claims alleged against Edwards.[40] Third, JenaValve's executives and Defendants' expert Mr. McWilliams testified that JenaValve's prospects of raising approximately $50 million in a series C investment round are good, further extending JenaValve's cash runway to PMA approval and beyond.[41] From that point, JenaValve could pursue another investment round or an initial public offering, either of which would provide further resources supporting JenaValve as its revenues from commercial sales grow.[42]

The September 26 deficiency letter: Defendants attempt to portray JenaValve's receipt of an FDA deficiency letter as a grave threat. But, as JenaValve's Chairman Jan Keltjens testified, deficiency letters are common—a fact confirmed by Dr. Kesselheim, who testified that 70-90% of medical device companies receive at least one during the regulatory process.[43] [redacted].[44] [redacted].[45] Ultimately,

[38] *See* Keltjens Day 5-AM 112:17-118:11; Kilcoyne Day 1-PM 72:25-73:5.
[39] *See infra* § XI.B; Keltjens Day 5-PM 27:15-20.
[40] *See infra* § III; Keltjens Day 5-PM 27:21-24.
[41] McWilliams Day 6-AM 122:18-123:6; *see infra* § XI.B.2.a.
[42] *See infra* § XI.B.2. Any cash bottlenecks JenaValve faces today are the result of Edwards' refusal to provide increased interim funding. *See infra* §§ III; XI.B.
[43] Keltjens Day 5-AM 119:15-120:3; Kesselheim Day 4-PM 20:19-23; *see infra* §§ V, XI.B.4.
[44] *See infra* § XI.B.4.
[45] Kilcoyne Day 1-PM 85:3-13; *see infra* § XI.B.

companies in JenaValve's position obtain PMA approval 81% of the time on average,[46] and Defendants' experts agree that PMA approval is likely.[47]

Trilogy's development: Contrary to Defendants' claims that Edwards is uniquely positioned to bring Trilogy to market at scale, the evidence shows that JenaValve's Trilogy is a device Edwards may struggle to develop. Edwards' expertise is with balloon-expanding valves made with bovine tissue, like its flagship TAVR-AS valve SAPIEN, not self-expanding porcine valves like Trilogy. Indeed, Edwards executives admit that Edwards tried and failed to develop a self-expanding TAVR valve.[48] Likewise, Edwards [redacted].[49] On its own, JenaValve has completed its ALIGN-AR trial, launched the ARTIST trial, [redacted], commercialized Trilogy in Europe, and reached the brink of PMA approval.[50]

Edwards' plans for ARTIST: Edwards claims that [redacted] yet the Court heard from JenaValve employees and TAVR doctors about their confidence in the safety of Trilogy and the importance of ARTIST to expand the treatable patient population.[51] In reality, Edwards sees little business sense [redacted].[52]

Edwards' acquisition of JC Medical: Edwards asserts that if it had not acquired JC Medical, the J-Valve technology would have been shut down. Yet when JC Medical's prior

[46] *See infra* § VIII.B.
[47] *See infra* § VIII.B; McWilliams Day 6-AM 100:2-16, 105:14-20.
[48] *See infra* § XI.D.
[49] *See infra* § XI.D.
[50] *See infra* § XI.B; Kilcoyne Day 1-PM 89:9-90:14.
[51] *See infra* §§ X.C.2, XI.B.4.
[52] *See infra* § X.D.

owner, Genesis Medtech, decided to shop JC Medical, multiple companies showed interest, including [redacted], and a venture capital fund.[53] [redacted].[54] Edwards moved more quickly than those other companies and provided a term sheet to JC Medical first—a term sheet mandating JC Medical cease other negotiations.[55] And Genesis/JC Medical was so confident in the value of the company and its negotiating position that it extracted a $25 million investment by Edwards into Genesis in addition to the putative $115 million sale price.[56] There is no evidence that Genesis would have abandoned an asset worth more than $115 million if the Edwards deal had fallen through; in other words, Edwards has not shown that J-Valve would have left the U.S. market unless Edwards had acquired it.[57]

Finally, Edwards remains adamant in its refusal to contemplate divesting JC Medical—an acquisition its CEO told the Court was "immaterial"—despite repeated requests from both JenaValve and the FTC.[58] This stubbornness illuminates its strategy: "to be the fat kid at the pie store . . . and take them both."[59]

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With Defendants abandoning any efficiencies, weakened competitor, or failing firm defenses, all that remains is to weigh the equities.[60] As demonstrated at the hearing, Edwards' promises of a faster Trilogy approval, increased innovation, fast followers, and increased output

[53] *See infra* § XI.C.
[54] *See infra* § XI.C; Larkin Day 2-AM 144:8-12.
[55] *See infra* § XI.C.
[56] PX1040-001; Turco Day 4-AM 92:13-94:21 (referencing PX1039-001).
[57] Regardless, the JC Medical acquisition is not the transaction being challenged here; the FTC is not aware of any case where a failing firm argument was deployed in these circumstances.
[58] Zovighian Day 2-PM 48:17-24, 79:16-80:13.
[59] Wood Day 2-AM 36:8-37:6
[60] *See infra* § XIII.

are illusory.[61] Meanwhile, the evidence of Edwards' unclean hands is concrete.[62] Defendants, in the name of equity, ask the Court to give Edwards total power over JenaValve, but Edwards [redacted].[63] Other powerful equities support the FTC: the nation's interest in the effective enforcement of the antitrust laws and continued competition between the only two firms in the U.S. TAVR-AR device market.[64]

Ultimately, the testimony of three CEOs—Bernard Zovighian (Edwards), Mark Turco (formerly JC Medical), and John Kilcoyne (JenaValve)—made plain that the Proposed Transaction is a bad deal for the TAVR-AR device market and, by extension, the over 100,000 U.S. patients suffering from severe aortic regurgitation. Mr. Zovighian admitted that Edwards' attempt to simultaneously acquire both U.S. TAVR-AR companies was "risky."[65] Edwards' plan, if the Proposed Transaction is blocked, [redacted]."[66] He conceded that Edwards has calculated no synergies from the Proposed Transaction[67] and that Edwards' touted increase in R&D was due to "higher performance based compensation expense partially offset by *decreased* investments in our transcatheter aortic valve innovations."[68] Despite Edwards' contention that Chinese companies

[61] *See infra* § XI.
[62] *See infra* § XIII.
[63] PX2373-001; Zovighian Day 2-PM 78:5-79:13.
[64] *See infra* § XIII.A.
[65] Zovighian Day 2-PM 44:22-24 (referencing PX1437-001).
[66] Zovighian Day 2-PM 45:15-21, 78:11-79:2 (referencing PX1437-001).
[67] Zovighian Day 2-PM 67:7-9.
[68] Zovighian Day 2-PM 67:7-9, 107:17-25 (emphasis added) (referencing PX6037-043).

may be "fast followers," Mr. Zovighian testified that clinical testing of Chinese medical devices lacks the scientific rigor of U.S. testing.[69]

Dr. Turco recounted how Edwards and JC Medical were "all aligned in avoiding HSR" laws governing the reporting of mergers to U.S. antitrust enforcers.[70] He explained how Edwards and JC Medical artificially lowered the value of the deal to sneak under the $119 million HSR threshold by diverting some of the purchase price to a $25 million investment in JC Medical's former parent.[71] To further conceal it, the transaction was not disclosed in Edwards' 10-Q to the SEC or announced publicly until well after it closed.[72]

And the Court heard from JenaValve's CEO that Edwards' concealment of its acquisition of JC Medical from JenaValve while it negotiated the Proposed Transaction constituted fraud.[73] Mr. Kilcoyne agreed that Edwards' "high stakes strategy" was a gamble that jeopardized the Proposed Transaction's chances of success.[74] He testified that Edwards threatened to cut off JenaValve's funding if it did not continue supporting Edwards' unyielding plan to own both companies.[75] He agreed that Edwards [redacted].[77] He admitted that no plans exist to integrate JenaValve into Edwards.[78] And he agreed that Trilogy will change lives, whether JenaValve is part of Edwards or an independent company.[79]

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[69] Zovighian Day 2-PM 70:6-19.
[70] Turco Day 4-AM 95:8-18 (referencing PX1479-001).
[71] *See infra* § XIII.E.
[72] *See infra* § XIII.E.
[73] Kilcoyne Day 1-PM 51:16-52:4 (referencing PX2371-002).
[74] Kilcoyne Day 1-PM 37:22-38:6, 38:14-39:13, 42:21-4 (referencing PX2373-001).
[75] Kilcoyne Day 1-PM 47:21-53:23.
[76] Kilcoyne Day 1-PM 43:5-13, 102:5-11.
[77] Kilcoyne Day 1-PM 55:6-9, 59:1-4.
[78] Kilcoyne Day 1-PM 54:2-10.
[79] Kilcoyne Day 1-PM 62:15-17.

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. The FTC Has Proven the Proposed Transaction Is Likely Substantially to Lessen Competition and Tends to Create a Monopoly

1. Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or . . . activity affecting commerce in any section of the country." 15 U.S.C. § 18. Section 7 is intended to arrest anticompetitive mergers "in their incipiency" and, accordingly, requires a prediction of the merger's likely impact on future competition. *United States v. Phila. Nat'l Bank* ("*PNB*"), 374 U.S. 321, 362 (1963) (quotation omitted); *United States v. Aetna, Inc.*, 240 F.Supp.3d 1, 79 (D.D.C. 2017) ("Analyzing the anticompetitive effects . . . necessarily 'focus[es] on the future.'") (quotation omitted). This incipiency standard requires that "any 'doubts are to be resolved against the transaction.'" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3rd Cir. 2016) (quoting *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989) (Posner, J.)).

2. The FTC is seeking a preliminary injunction under Section 13(b) of the FTC Act. 15 U.S.C. § 53(b). "Section 13(b) provides for the grant of a preliminary injunction where such action 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. Sysco Corp.*, 113 F.Supp.3d 1, 22 (D.D.C. 2015) (quotation omitted); *see FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001) (Section 13(b) uses a "unique public interest standard . . . rather than the more stringent, traditional equity standard for injunctive relief.") (quotations omitted).

3. The FTC is not asking this Court to permanently enjoin the Proposed Transaction, only to preserve the status quo and stave off consumer harm until the Commission has exercised its statutory authority to hold an administrative trial. *Heinz*, 246 F.3d at 713-14. At this juncture, the Commission "is not required to establish that the proposed merger would in fact violate Section

7 of the Clayton Act." *Id.*; *see also FTC v. Arch Coal*, 329 F.Supp.2d 109, 157 (D.D.C. 2004) (holding the Commission need only show a "reasonable probability that the challenged transaction[] may substantially lessen competition") (quotation omitted); *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1036 (D.C. Cir. 2008) (Brown, J.) ("[A]t this preliminary phase [the FTC] just has to raise substantial doubts about a transaction.").

II. The Parties to the Proposed Transaction

4. Edwards, headquartered in Irvine, CA, is a global supplier of medical devices for treating structural heart disease.[80] Through its subsidiary, JC Medical, which it acquired on July 22, 2024,[81] Edwards is developing J-Valve, a TAVR-AR device. Edwards began enrolling patients in the JOURNEY pivotal trial in October 2024.[82] [redacted][83] [redacted][84] JC Medical was founded in 2007 and, prior to Edwards' acquisition, was headquartered in Burlingame, CA, with separate U.S./North America and China operations.[85] Its CEO, Mark Turco, was based in Burlingame.[86] JC Medical began U.S. implants of J-Valve in 2018, began an FDA-approved EFS in 2023, and received an IDE for a U.S. pivotal trial in May 2024.[87]

5. JenaValve, also headquartered in Irvine, CA, was founded in 2005 to develop a TAVR-

[80] PX6002-001, 043.
[81] Zovighian Day 2-PM 46:12-15.
[82] PX1263-001; *see also* Concepcion Day 3-PM 15:12-16:5, 17:4-9.
[83] Concepcion Day 3-PM 18:23-22:10.
[84] Wood Day 2-AM 105:6-13, 106:12-15.
[85] Turco Day 4-AM 78:2-6, 78:16-22, 97:23-98:8; PX1048-007.
[86] Turco Day 4-AM 79:2-5, 97:23-98:8; PX1048-007.
[87] Turco Day 4-AM 79:8-11, 79:14-20, 80:2-9; *see* PX1171-001; PX1011-006.

AR device.[88] JenaValve successfully completed its ALIGN-AR pivotal trial,[89] which studied Trilogy in high-risk ssAR patients, published results for the initial patient cohort in March 2024 and extended results for an additional 520 patients in November 2025,[90] [redacted]. [91] [redacted] [92] JenaValve is actively enrolling patients in JenaVAD and the ARTIST trial, both intended to expand Trilogy's addressable patient population by studying patients with LVADs and patients at low and intermediate surgical risk, respectively. [93]

III. Proposed Transaction and Simultaneous Acquisition of JC Medical

6. On July 23, 2024, Edwards agreed to acquire JenaValve for approximately $945 million.[94] The day before, Edwards agreed to acquire the U.S./North America business of JenaValve's competitor JC Medical.[95] Edwards executed these deals to pursue its strategy of acquiring the only two AR-dedicated technologies in the United States.[96]

7. Edwards deliberately concealed the simultaneous acquisitions from its counterparties for "competitive reasons."[97] Mr. Kilcoyne testified that if JenaValve had known about the J-Valve acquisition, it "more than likely" would not have agreed to the same terms.[98] He believes Edwards acted in bad faith.[99] Ensuring deal certainty was a high priority to JenaValve during

[88] Kilcoyne Day 1-AM 82:16-19.
[89] JenaValve continues to enroll patients in ALIGN-AR through the FDA's CAP. Kilcoyne Day 1-AM 112:13-23.
[90] DX0297-003.
[91] PX2550-001.
[92] Kilcoyne Day 1-PM 85:3-13; *see also* Spadaro Dep. 146:10-17.
[93] Kilcoyne Day 1-AM 90:17-91:2; Pinto Day 4-AM 5:24-6:12; Chetcuti Day 6-AM 40:15-21.
[94] Zovighian Day 2-PM 46:19-21; PX6002-041.
[95] Zovighian Day 2-PM 46:12-15.
[96] Zovighian Day 2-PM 46:22-25; PX1530-014.
[97] Zovighian Day 2-PM 48:25-49:9; Kilcoyne Day 1-PM 28:15-22.
[98] Kilcoyne Day 1-PM 38:14-39:13 (referencing PX2373-001).
[99] Kilcoyne Day 1-PM 49:5-13.

negotiations, but Edwards' secret acquisition of J-Valve threatened that certainty.[100]

8. Edwards' concealment efforts included intentionally structuring the JC Medical transaction to fall below the HSR Act's value-of-transaction threshold.[101] This allowed Edwards to close the JC Medical deal without pre-closing antitrust regulatory review.[102]

9. Edwards also concealed its acquisition of JC Medical from the public. Edwards announced the proposed JenaValve acquisition in a press release and securities filing,[103] but did not disclose JC Medical's name or that it had acquired another company in the TAVR-AR space.[104] As Mr. Zovighian testified, there is nothing in Edwards's 10-Q securities filing to lead an investor to know that Edwards bought two companies in the TAVR-AR space.[105]

10. JenaValve and JC Medical executives recognized the competitive implications of Edwards' strategy. A JenaValve executive wrote, "[t]he only real competition is J-valve, and they are now part of Edwards."[106] When congratulated on being acquired by Edwards, Dr. Turco responded, "Thank you[.] However, interesting times as EW also has acquired a competitor Jena Valve."[107] JenaValve employees could only think of one plausible reason why Edwards would purchase both companies: "Because they're buying the whole AR market."[108] Mr. Keltjens was so astounded that, upon learning of the JC Medical transaction, he declared it "fake news."[109] In a September 2024 "town hall," Mr. Wood announced the AR acquisitions to Edwards' employees

[100] Kilcoyne Day 1-PM 37:6-38:13.
[101] *See infra* § XIII.E.
[102] Turco Day 4-AM 92:13-94:21 (referencing PX1039-001).
[103] Zovighian Day 2-PM 47:1-6, 47:18-21; PX6002-041.
[104] Zovighian Day 2-PM 47:22-48:16; Bobo Day 2-PM 137:13-138:2; PX6002-042; *see also* Wood Day 2-AM 30:20-23.
[105] Zovighian Day 2-PM 48:12-16.
[106] PX2191-003.
[107] PX1053-001.
[108] PX2432-002.
[109] PX2198-002.

using an AI-generated image of a pie-eating toddler to communicate that Edwards decided it was going to be a fat kid at the pie store and take both JC Medical and JenaValve.[110]

11. JenaValve's CEO was concerned about Edwards' TAVR-AR acquisition strategy on three accounts: first, putting two TAVR-AR companies together would increase antitrust scrutiny and delay the proposed JenaValve acquisition; second, the JC Medical deal would distract Edwards from executing on JenaValve's Trilogy PMA and thus adversely impact the PMA milestone agreement in the JenaValve Merger Agreement; and third, that J-Valve's sales would cannibalize sales of Trilogy credited to its commercial earnout.[111] JenaValve was also concerned that Edwards' acquisition of J-Valve would slow down JenaValve's forward momentum, putting it in "purgatory," leading to delays in patient access to Trilogy and giving J-Valve a head start.[112]

12. JenaValve accused Edwards of keeping the J-Valve acquisition secret and acting in bad faith by refusing to discuss divesting J-Valve.[113] JenaValve's attorneys wrote to Edwards' attorneys that: "In these circumstances, and given that we would not be in this situation but for your concealed deal, we expect a Court of Equity to oblige Edwards to divest."[114] JenaValve also accused Edwards of fraud for their handling of the simultaneous acquisitions.[115] JenaValve's lawyers wrote to Edwards' attorneys: "In short, this narrative is pretextual and offered in a bad faith effort to deflect from Edwards' fraud in signing its deal with JenaValve while concealing from JenaValve and its advisors Edwards' near-simultaneous acquisition of J.C. Medical."[116]

13. Edwards responded by threatening to cut off JenaValve's interim funding and require

[110] Wood Day 2-AM 36:24-37:6 (referring to PX1262-072).
[111] Kilcoyne Day 1-PM 31:3-32:17; *see also* PX2162-001.
[112] Kilcoyne Day 1-PM 43:5-44:10; PX2373-001.
[113] Kilcoyne Day 1-PM 48:9-49:13; PX2370-002.
[114] PX2370-002.
[115] Kilcoyne Day 1-PM 52:1-4; PX2371-002.
[116] PX2371-002.

immediate repayment.[117] That would create a "large crisis," as JenaValve does not have sufficient funds to repay Edwards and does not have any other source of external income.[118] [redacted].[119]

14. Edwards rebuffed JenaValve's requests that it divest JC Medical to facilitate closing the JenaValve transaction. Mr. Kilcoyne testified that he believed the Proposed Transaction would be more likely to close if Edwards were to divest JC Medical.[120] The FTC wrote that divesting JC Medical would resolve antitrust issues.[121] Edwards' response "was a hard no."[122]

15. Mr. Bobo testified Edwards would not divest JC Medical because Edwards made minor modifications to J-Valve post-acquisition.[123] Being able to cover all patients—that is, not having to develop Trilogy XL—was an independent reason to refuse to divest.[124]

16. [redacted].[125] [redacted].[126] Divestiture would thwart Edwards' plan "to be a fat kid at the pie store and . . . take them both."[127]

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[117] Kilcoyne Day 1-PM 53:3-23; PX2473-002.
[118] Keltjens Day 5-PM 28:16-25.
[119] Kilcoyne Day 1-PM 104:20-105:2.
[120] Kilcoyne Day 1-PM 42:17-20.
[121] PX0061-002.
[122] Bobo Day 3-AM 39:6-12; Kilcoyne Day 1-PM 35:23-36:15, 41:24-43:4; PX2373-001; PX2346-002; PX0061-001; PX2372-004.
[123] Bobo Day 3-AM 39:6-40:3, 66:22-67:3.
[124] Bobo Day 3-AM 39:6-40:13.
[125] Mem. Op. Granting Pl.'s Mot. to Compel. Disc. Resps. from Def. JenaValve Technology, Inc. 5, Dkt. No. 78.
[126] Zovighian Day 2-PM 79:16-80:13.
[127] Wood Day 2-AM 36:8-37:6.

IV. Aortic Regurgitation Disease and Treatment

17. Aortic valve diseases are debilitating and potentially fatal. Aortic regurgitation is characterized by a failure of the valve's leaflets to fully close after each heartbeat, resulting in blood flowing back through the valve.[128] More than 100,000 Americans suffer from ssAR.[129] Left untreated, one in four patients with ssAR die within a year and over 70% will die within five.[130]

18. The only FDA-approved AR treatment is open-heart surgery (i.e., SAVR).[131] SAVR is a highly invasive procedure as the doctor surgically opens the chest, stops the heart, cuts open the aorta, and replaces the malfunctioning native valve with a manufactured replacement.[132] SAVR requires several days in the hospital and months of recovery.[133]

19. AR patients at high risk for mortality and complications with surgery are poor candidates, or altogether ineligible, for SAVR.[134] Thus, high-risk AR patients often go untreated.[135] Patients that are eligible for SAVR will also sometimes go untreated because they are afraid to undergo surgery.[136] Dr. Vahl testified SAVR-eligible patients have declined surgical treatment and go untreated due to fear of open-heart surgery.[137] Ms. Sharma testified that "patients [are] often very intervention avoidant. . . . [W]hen the only option is someone's chest being cracked open and their heart being stopped . . . a lot of patients just don't want to get any

[128] PX2327-005; PX6006-001; DX0297-001-002.
[129] PX1010-004; PX1394-003.
[130] PX2193-013; PX6006-001.
[131] PX6006-001; DX0297-001-002; PX1390-001.
[132] Pinto Day 3-PM 123:15-23; Kesselheim ¶¶ 24-25.
[133] Pinto Day 3-PM 123:15-23; Kesselheim ¶¶ 24-25.
[134] Kilcoyne Day 1-AM 84:4-85:17 (referencing PX2327-006).
[135] PX6006-001; Bierman Day 3-AM 83:7-84:1 (referencing PX1390-001).
[136] Vahl Day 4-AM 66:12-67:3.
[137] Vahl Day 4-AM 66:20-67:3.

intervention."[138]

20. There is no commercially available alternative to surgery for U.S. AR patients.[139] JenaValve's CEO testified that medical management, i.e., the use of pharmaceuticals, is not an effective treatment for ssAR.[140] The lack of therapeutic options and patients' aversion to open-heart surgery leads to nearly 75% of AR patients going untreated.[141]

21. TAVR provides a minimally invasive treatment option for patients.[142] TAVR valves are attached to a catheter and guided to the aorta for implantation.[143] TAVR valves can be implanted via a transfemoral or transapical delivery.[144] Transfemoral procedures are less invasive than transapical procedures.[145] The transapical access requires an incision into the chest wall and implantation directly through the apex of the heart, while transfemoral devices are inserted via the femoral artery,[146] and a "small incision in the groin."[147] Transapical requires prolonged recoveries and has poorer clinical outcomes.[148] Physicians thus prefer transfemoral devices and are not interested in transapical devices to treat AR.[149] "[D]ue to a lack of physician interest" from U.S. doctors in transapical devices,[150] Trilogy changed from transapical to transfemoral delivery in 2014.[151]

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[138] Sharma Day 5-PM 129:15-130:15, 151:22-152:2.
[139] PX1390-001; PX1391-001.
[140] Kilcoyne Day 1-AM 84:22-85:2; PX2327-006.
[141] PX1010-004; PX1394-003.
[142] Pinto Day 3-PM 125:20-126:15; PX6006-001; DX0297-001-002.
[143] Pinto Day 3-PM 127:10-127:21.
[144] PX6006-002.
[145] Kilcoyne Day 1-PM 6:23-7:3.
[146] Kilcoyne Day 1-PM 6:10-22.
[147] Vahl Day 4-AM 61:5-25.
[148] Vahl Day 4-AM 61:5-25; Madrid Dep. 141:25-142:7.
[149] Kilcoyne Day 1-PM 9:9-15; Wood Day 2-AM 49:20-22; PX1292-001.
[150] PX2457-040.
[151] PX2468-002.

22. TAVR was first developed to treat AS, a disease characterized by calcium buildup that prevents the aortic valve from opening fully.[152] TAVR-AS valves are not suitable for treating AR.[153] When used for AR, AS valves dislodge—a potentially fatal complication.[154] To solve this, JenaValve and JC Medical developed TAVR-AR devices with unique anchoring systems that clip onto the heart valve's native leaflets.[155]

23. Edwards' attempts to develop its own TAVR-AR device failed.[156]

V. Medical Device Development and the FDA Regulatory Approval Process

24. Medical device development begins with a preclinical phase. The FDA does not regulate the preclinical development process, and a device being in preclinical development does not indicate whether a developer may eventually seek FDA approval.[157] Only a small fraction of devices in development will ultimately seek FDA approval.[158]

25. The FDA categorizes all medical devices into three levels of risk: Class I or low-risk; Class II or moderate-risk; and Class III or high-risk. High-risk devices sustain life, prolong life, or put a patient at substantial risk of harm.[159] TAVR-AR and AS devices are high-risk devices, and subject to the FDA's strictest safety and effectiveness standards to obtain FDA approval.[160]

26. To begin U.S. human clinical testing for high-risk devices, a manufacturer needs an IDE from the FDA.[161] Human clinical testing may ultimately support a device's FDA

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[152] Wood Day 2-AM 61:4-21.
[153] *See infra* § VII.C.2; PX6006-001, -002, -003.
[154] *See infra* § VII.C.2; Kilcoyne Day 1-AM 86:9-11; PX8000 Kesselheim ¶ 29.
[155] DX0297-003.
[156] Zovighian Day 2-PM 67:13-15.
[157] Kesselheim Day 4-PM 15:16-24.
[158] Kesselheim Day 4-PM 15:19-24.
[159] Kesselheim Day 4-PM 12:10-18; PX8000 Kesselheim ¶¶ 37-39.
[160] Kesselheim Day 4-PM 12:19-22.
[161] Kesselheim Day 4-PM 15:25-16:7; PX8000 Kesselheim ¶¶ 44-45; Wood Day 2-AM 95:8-11.

approval.[162]

27. Obtaining an IDE is a complicated process requiring FDA review of substantial preclinical data (from laboratory or animal studies) and study designs.[163] Once the FDA approves an IDE application, the device traditionally moves to a pilot or feasibility study. An EFS is conducted in small patient cohorts to assess if the device functions as intended[164] and guide the design of subsequent pivotal studies.[165]

28. After a promising EFS, a device moves into pivotal trials with FDA permission.[166] Pivotal trials are larger, more rigorous studies that can involve hundreds of patients and form the basis for FDA approval.[167] If the pivotal trials are successful, the results are compiled, along with results from previous preclinical or clinical studies, manufacturing information, and proposed labeling, into a PMA application for submission to the FDA.[168]

29. The FDA has six months to review the PMA application, unless the FDA has questions or requires additional information.[169] The FDA conveys questions about a PMA application through a formal document called a deficiency letter.[170] Deficiency letters are a normal part of the PMA review, and 70 to 90% of applications receive deficiency letters.[171]

30. Overall, the FDA approval process can take 5 to 10 years, and 8.5 years on average,

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[162] Kesselheim Day 4-PM 16:8-13.
[163] Kesselheim Day 4-PM 16:14-20, 18:5-16, 87:8-14; PX8000 Kesselheim ¶ 45; *see also* Wood Day 2-AM 38:24-39:2 (agreeing that the FDA sets "a higher bar to get approval in the United States compared to other regulatory bodies in the rest of the world").
[164] Kesselheim Day 4-PM 17:5-15; Wood Day 2-AM 39:9-40:11.
[165] Kesselheim Day 4-PM at 17:5-15.
[166] PX8000 Kesselheim ¶ 49; Wood Day 2-AM 41:8-14.
[167] Kesselheim Day 4-PM 18:17-22, 19:6-10.
[168] Kesselheim Day 4-PM 19:11-20.
[169] Kesselheim Day 4-PM 20:5-13.
[170] Kesselheim Day 4-PM 20:14-18.
[171] Kesselheim Day 4-PM 20:19-23.

from IDE approval to PMA approval.[172] Dr. Bailey agreed with this timing, citing to the same study Dr. Kesselheim relied upon in his report.[173] On average it can take from six months to two years for the FDA to review a PMA application.[174] On average it takes about four to six years from the start of pivotal trials to PMA approval.[175]

VI. Competition and Innovation Among TAVR-AS Devices

31. Contrary to Edwards' assertions, the TAVR-AS market developed from competition among multiple TAVR-AS companies.[176] When SAPIEN initially gained FDA approval, Medtronic had an ongoing clinical trial in the United States for its TAVR-AS device.[177]

32. Dr. Kesselheim analyzed PMA supplements and found that TAVR-AS innovation continued post-PMA approval across manufacturers.[178] TAVR-AS PMA panel-track supplements—used for the most significant device changes—first appeared after Medtronic's CoreValve's PMA approval and occurred most often after both CoreValve and Edwards' Sapien products (XT and 3) were approved.[179] He concluded that, likewise, with multiple manufacturers of TAVR-AR devices, it is reasonable to expect that TAVR-AR devices will experience a substantial number of post-approval changes akin to TAVR-AS.[180]

33. In TAVR-AS, Medtronic and Edwards compete with similar "playbooks," including through high-touch service models[181] and aggressive head-to-head clinical trials to the benefit of

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[172] Kesselheim Day 4-PM 12:1-9, 21:7-13; PX8000 Kesselheim ¶ 60, Table 2.
[173] Bailey Day 5-PM 29:8-14.
[174] Kesselheim Day 4-PM 20:24-21:6.
[175] Kesselheim Day 4-PM 22:3-8.
[176] *See* Wilson Day 5-AM 48:16-50:1; PX8001 Wilson ¶¶ 106-08.
[177] Kesselheim Day 4-PM 27:14-17; Vahl Day 4-AM 45:22-46:3, 46:7-9; PX8000 Kesselheim ¶ 28.
[178] Kesselheim Day 4-PM 13:16-24, 24:15-25:3, 27:18-25; PX8000 Kesselheim ¶¶ 102-06, 115-19, Figure 4.
[179] Kesselheim Day 4-PM 26:24-27:3; PX8000 Kesselheim ¶¶ 120-21.
[180] Kesselheim Day 4-PM 28:1-10.
[181] Wood Day 2-AM 21:10-14; PX1271-013; PX1275-009.

TAVR-AS patients.[182] For example, Edwards and Medtronic's TAVR-AS trials expanded TAVR-AS to intermediate and low risk patients who might otherwise not receive treatment because of unwillingness to undergo surgery.[183]

34. Edwards seeks to maintain its number one position in the TAVR-AS market through investment in R&D.[184] [redacted].[185]

35. TAVR-AS competition has benefited consumer pricing. For example, Edwards notes that "price pressure is likely to increase with more players" thereby impacting its "premium price position."[186] Similarly, "after Medtronic CoreValve entry," Edwards anticipated needing to "increase price flexibility up to [redacted] off list in a structured and defensible way" and that its SAPIEN sales would have high growth only "until Medtronic CoreValve pressure" occurred.[187]

VII. The Relevant Product Market Is U.S. TAVR-AR Devices

A. Legal Standard

36. The relevant product market is the "line of commerce" or "activity affecting commerce" affected by a proposed merger. *Brown Shoe v. United States*, 370 U.S. 294, 324 (1962); 15 U.S.C. § 18. Courts define a relevant market as an analytical tool to ascertain the "locus of competition." *United States v. Bertelsmann SE & Co.*, 646 F.Supp.3d 1, 24 (D.D.C. 2022) (quoting *Brown Shoe*, 370 U.S. at 320-21). Ultimately, market definition is "a pragmatic,

[182] Wood Day 2-AM 22:16-22, 23:25-26:4; PX1271-013.
[183] Wood Day 2-AM 24:17-25:3; PX1273-004, 006; Sharma Day 5-PM 129:15-130:15, 151:22-152:2.
[184] Sirimanne Day 5-PM 105:13-25, 108:5-10; PX1229-001.
[185] Larkin Day 2-AM 128:13-24, 132:1-9.
[186] PX1275-004, 007.
[187] PX1276-007, 017.

factual" analysis and "not a formal, legalistic one." *Brown Shoe*, 370 U.S. at 336.

37. In Section 13(b) proceedings, it is "not necessary" for Plaintiffs "to *prove* the existence of the [relevant] market." *FTC v. IQVIA Holdings Inc.*, 710 F.Supp.3d 329, 368 (S.D.N.Y. 2024) (quoting *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1041 (D.C. Cir. 2008)) (emphasis in original). Instead, Plaintiffs need only "rais[e] some question of whether [the alleged market] is a well-defined market." *Whole Foods*, 548 F.3d at 1037.

38. "[T]he relevant geographic market is the area 'to which consumers can practically turn for alternative sources of the product and in which the antitrust defendants face competition.'" *FTC v. Cardinal Health, Inc.*, 12 F.Supp.2d 34, 49 (D.D.C. 1998) (quotations omitted). Here, the United States is the relevant geographic market in which to analyze the effects of the proposed transaction because the United States has unique regulatory requirements, and American physicians and patients require TAVR-AR devices approved by U.S. regulators.[188]

39. A relevant product market's "'boundaries' are determined by the 'reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.'" *FTC v. Tronox Ltd.*, 332 F.Supp.3d 187, 198 (D.D.C. 2018) (quoting *Brown Shoe*, 370 U.S. at 325). That is, "courts look at 'whether two products can be used for the same purpose, and, if so, whether and to what extent purchasers are willing to substitute one for the other.'" *United States v. H&R Block*, 833 F.Supp.2d 36, 51 (D.D.C. 2011) (citation omitted).

40. In *Brown Shoe*, the Supreme Court set forth "practical indicia" for defining a relevant product market. 370 U.S. at 325. These factors, as described in *Brown Shoe* and its progeny, include "the product's peculiar characteristics and uses, unique production facilities, distinct

[188] PX2320-018 [redacted] "); *see also supra* § V.

customers, distinct prices," "industry or public recognition" of the market, and how ordinary-course documents portray the reality of the market. *Id.*; *Sysco*, 113 F.Supp.3d at 27; *Aetna, Inc.*, 240 F.Supp.3d at 21; *United States v. H&R Block*, 833 F.Supp.2d at 51. "All the factors need not be satisfied for the Court to conclude that the FTC has identified a relevant market." *IQVIA*, 710 F.Supp.3d at 355. Here, the *Brown Shoe* factors demonstrate that TAVR-AR devices constitute an antitrust market. Defendants' pre-trial brief entirely failed to engage with the *Brown Shoe* factors.[189]

41. In *Illumina, Inc. v. FTC*, the Fifth Circuit held that the FTC alleged a viable antitrust market for cancer-detection tests, including both firms in clinical trials and firms with commercialized products, because they were in active competition with each other. 88 F.4th 1036, 1049-52 (5th Cir. 2023). To exclude products in development when "there is indisputably ongoing competition to bring additional products to market" would "directly contravene the purpose of Section 7—'to arrest anticompetitive tendences in their incipiency.'" *Id.* at 1050 (quoting *PNB*, 374 U.S. at 362). As in *Illumina*, evidence shows "there is indisputably ongoing competition" between Edwards and JenaValve.[190]

42. Similarly, the Merger Guidelines recognize that, when considering harm to innovation, "the Agencies may define relevant antitrust markets around the products that would result from that innovation if successful, even if those products do not yet exist." Merger Guidelines § 4.3.D.7. Consistent with this approach, *Illumina* affirmed a relevant market defined around the products "developers reasonably sought to achieve, not what they currently had to offer." *Illumina*, 88 F.4th at 1050. In this matter, the products—TAVR-AR devices for U.S.

[189] Defs.' Opp'n to Pl.'s Mot. for Prelim. Inj. 29-31, Dkt. No. 115.
[190] *See infra* § X.

patients—exist today. Moreover, Defendants agree that Edwards and JenaValve are reasonably seeking the same end goal: PMA approval and commercialization of their devices in the United States.[191]

43. In other contexts, courts found that companies can compete with commercialized products in a relevant product market before making commercial sales. *See United States v. El Paso Natural Gas Co.*, 376 U.S. 651, 658 (1964) ("Pacific Northwest, though it had no pipeline into California, is shown by this record to have been a substantial factor in the California market at the time it was acquired by El Paso."); *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1215 (11th Cir. 2012) ("[T]he pre-acquisition market activity by the acquired company—although resulting in no actual sales—had a substantial, actual pro-competitive effect on the market."); *FTC v. Alliant Techsystems Inc.*, 808 F.Supp. 9, 11-16 (D.D.C. 1992) (enjoining merger of 120mm tank ammunition manufacturers in advance of the Army's 1994 competitive bid process).

44. "When determining the relevant product market, courts often pay close attention to the defendants' ordinary course of business documents," which provide "strong evidence" of the relevant product market. *H&R Block*, 833 F.Supp.2d at 52-53 (finding defendants' ordinary-course documents identify its "primary competitors, that it has tracked their marketing, product offerings, and pricing, and that it has determined its own pricing and business strategy in relation to those companies" products); *see IQVIA*, 710 F.Supp.3d at 362-63 (same). Courts delineate the bounds of a relevant market by examining a company's "own internal documents" to find who the "company viewed [] as being in active competition" with it. *Illumina*, 88 F.4th at 1050; *United States v. Bazaarvoice, Inc.*, 2014 WL 203966, *66 (N.D. Cal. Jan. 8, 2014) (holding that "Bazaarvoice's recognition that PowerReviews was its primary competitor supports the

[191] Bailey Day 6-PM 33:19-34:5, 59:5-14.

determination that R & R platforms are the relevant product market.").

45. "In evaluating reasonable interchangeability, 'the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes.'" *IQVIA*, 710 F.Supp.3d at 368 (quoting *Sysco*, 113 F.Supp.3d at 26). Further, the inquiry does not look at all products that are interchangeable for any purpose—only products "reasonably interchangeable by consumers for the same purpose." *Optronic Techs., Inc. v. Ningbo Sunny Elec. Co.*, 20 F.4th 466, 482 (9th Cir. 2021). "In other words, the existence of a larger market within which two products compete does not necessarily mean that they are reasonably interchangeable substitutes for one another." *IQVIA*, 710 F.Supp.3d at 368; *see FTC v. Staples, Inc.*, 970 F.Supp. 1066, 1075 (D.D.C. 1997). "[T]he viability of such additional markets does not render the one identified by the government unusable." *IQVIA*, 710 F.Supp.3d at 368 (quoting *Bertelsmann*, 646 F.Supp.3d at 28).

46. In addition to the *Brown Shoe* factors, courts may use the hypothetical monopolist test ("HMT") to define a relevant product market, *see, e.g.*, *H&R Block*, 833 F.Supp.2d at 51-52, though they are not required to do so, *see Illumina*, 88 F.4th at 1048-50 (relying on *Brown Shoe* factors, without referring to the HMT, to determine the relevant market). The HMT asks whether, assuming all products in the candidate market were controlled and sold by a monopolist, that hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price ("SSNIP"), typically five percent, on one of the merging parties' products. If so, those products constitute a relevant market. *See, e.g.*, *H&R Block*, 833 F.Supp.2d at 51-52.

47. Both qualitative and quantitative evidence may be used to conduct the HMT. Merger Guidelines § 4.3.C. Courts routinely find that "reliance on qualitative economic evidence [is] sufficient to define the market, because 'there appears to be no support in the caselaw for the

claim that such a technical analysis is always required.'" *United States v. Google LLC*, 747 F.Supp.3d 1, 109 (D.D.C. 2024) (citing *McWane, Inc. v. FTC.*, 783 F.3d 814, 829 (11th Cir. 2015)); *see also Bazaarvoice*, 2014 WL 203966, at *67 (applying HMT based on testimony, not quantitative analysis). Whether applying the *Brown Shoe* indicia or the HMT, the relevant product market to assess the Proposed Transaction is TAVR-AR devices.

B. TAVR-AR Devices Is the "Line of Commerce" Affected by the Proposed Transaction

48. TAVR-AR devices qualify as a "line of commerce." *See* 15 U.S.C. § 18. Both Edwards and JenaValve presently supply these devices to U.S. patients: around 850 U.S. patients have received Trilogy valves,[192] and J-Valve has been implanted in U.S. patients through clinical trials.[193] JenaValve estimated the total addressable market ("TAM") for extreme and high risk ssAR patients in 2025, which Mr. Kilcoyne confirmed at approximately [redacted].[194] Similarly, JenaValve estimated the TAM for intermediate and low risk ssAR patients in 2025 to be approximately [redacted][195]

C. Practical Indicia Establish TAVR-AR Devices as a Relevant Product Market

49. TAVR-AR devices have peculiar characteristics and uses, distinct customers and pricing, and industry recognition as a distinct product market.

1. Industry Recognition

50. Defendants' testimony and ordinary-course documents support TAVR-AR devices as a separate and distinct market.[196] For example, Defendants' executives calculate TAVR-AR

[192] Pinto Day 3-PM 75:9-17.
[193] *See, e.g.*, Concepcion Day 3-PM 15:12-17, 17:7-9.
[194] Kilcoyne Day 1-AM 89:25-90:13 (referencing PX2327-008).
[195] Kilcoyne Day 1-AM 90:14-16, 91:3-16 (referencing PX2327-008).
[196] Sun Day 3-PM 59:12-15 (referencing PX2052-002); Kilcoyne Day 1-AM 84:8-86:15 (referencing PX2327-006); PX1394-002-006; PX1001-001.

device market share using "USA TAVR-AR Case Volumes" and assess the market opportunity for the "AR patient population."[197]

51. Additionally, physicians who have performed TAVR-AR procedures recognize TAVR-AR devices as distinct from other methods of treatment for AR.[198]

2. Peculiar Characteristics and Uses

52. TAVR-AR devices have peculiar characteristics and uses that differentiate them from other treatments. As explained in Section IV, TAVR provides a less invasive option than SAVR for AR patients and is the only option for patients at high risk for surgery.[199] TAVR offers better patient outcomes because of "shorter hospital stays and reduced ICU utilizations. This is due to faster recovery associated with the minimally invasive nature of TAVR compared to SAVR."[200]

53. As discussed in Section IV, TAVR-AR devices like Trilogy and J-Valve are specifically and uniquely designed to anchor to the native leaflets of the aortic valve, unlike TAVR-AS devices which instead rely on calcium buildup for anchoring.[201] The off-label use of TAVR-AS devices is not comparable and carries a high risk of complications, including death.[202]

3. Distinct Customers

54. AR patients and the interventional cardiologists who treat them via TAVR are distinct customers. A September 2024 Edwards Board of Directors presentation analyzed the AR patient

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[197] Turco Day 4-AM 73:16-74:15 (referencing PX1049-010); *see also* Kilcoyne Day 1-AM 89:25-91:16 (referencing PX2327-008).
[198] Vahl Day 4-AM 59:9-18; PX3081-002-003; PX6006-001; Pinto Day 3-PM 85:10-15 (referencing PX2109-006).
[199] Kilcoyne Day 1-AM 85:3-17 (referencing PX2327-006); PX3081-002-003; PX0033-006.
[200] PX3081-003.
[201] Vahl Day 4-AM 60:11-21; McCabe Dep. 36:10-37:3; PX6006-001 (outcomes for AR patients treated with TAVR-AS are "unsatisfactory" as the absence of calcium on the leaflets leads to "suboptimal procedural success rates.").
[202] Kilcoyne Day 1-AM 85:21-86:11 (referencing PX2327-006); Vahl Day 4-AM 59:9-18 *see also* PX2434-001; PX6006-001; PX0033-006; Pinto Day 3-PM 85:10-15 (referencing PX2109).

population and identified a distinct group of around 100,000 AR patients over 65 years of age with ssAR and potentially eligible for TAVR-AR clinical trials.[203]

4. Distinct Pricing

55. Defendants have adopted distinct pricing strategies for their TAVR-AR devices that assume premium prices, reflecting the absence of competitive pressure from non-TAVR-AR products. Both JenaValve and Edwards currently charge clinical trial sites for their devices, and both have contemplated premium pricing post-FDA approval.[204] JenaValve plans to increase the price of Trilogy from the current [redacted] at launch, as it believes "the market will bear that higher price" when Trilogy is the only commercially available U.S. device[205] Edwards has also projected a "go-to-market" "target premium pricing for dedicated AR TAVR product."[206]

5. Economic Analysis Supports TAVR-AR Devices as the Relevant Product Market

56. Plaintiff's economic expert, Dr. Wilson, conducted the HMT to determine the appropriate relevant market and concluded that consumers would not switch away from TAVR-AR devices when faced with a SSNIP.[207] The record is unambiguous that a hypothetical monopolist of TAVR-AR products could profitably impose a SSNIP on one of the devices; other forms of treatment, such as off-label TAVR-AS devices, SAVR, and medical management, are not close substitutes for TAVR-AR devices.[208]

57. Defendants' expert, Dr. Bailey, did not dispute Dr. Wilson's conclusion that other

[203] PX1078-050; *see also id*. at 028.
[204] Kilcoyne Day 1-AM 93:2-94:6 (referencing PX2303-015); Bierman Day 3-AM 78:7-79:19 (referencing PX1394-035); *see also* Kereiakes Dep. 32:7-10, 32:19-22, 33:7-34:1; *see* Wood Day 2-AM 60:3-9.
[205] Kilcoyne Day 1-AM 93:24-94:6 (referencing PX2303-015).
[206] Bierman Day 3-AM 78:7-79:19 (referencing PX1394-035).
[207] Wilson Day 5-AM 22:22-23:17; PX8001 Wilson ¶¶ 43-50.
[208] Wilson Day 5-AM 23:18-25:6; PX8001 Wilson ¶¶ 46-48.

forms of treatment are not close substitutes for TAVR-AR devices. Dr. Bailey agrees that it is possible to have a single relevant market that includes both R&D and commercialization of a product, and that such an approach is consistent with the Merger Guidelines.[209]

58. While Dr. Bailey posited three different potential "groupings" of markets for TAVR-AR, she conceded that she "wasn't defining a relevant market" and that she did not undertake any analysis to determine whether her "groupings" actually constitute relevant antitrust markets.[210] Her "groupings" are not the relevant antitrust market defined by Dr. Wilson.[211]

D. The Relevant Geographic Market Is the United States

59. The FDA serves as the gatekeeper for high-risk medical devices in the United States.[212] U.S. physicians cannot implant TAVR-AR devices in patients without the necessary FDA approval.[213]

60. The Defendants' ordinary-course documents distinguish the U.S. TAVR-AR market from other geographies.[214] Internal Edwards presentations tracking the TAVR-AR space demonstrate that only JenaValve and JC Medical are on the path to FDA approval and that no other devices are undergoing U.S. clinical studies.[215]

61. Third-party testimony is consistent with a U.S. geographic market. For example, [redacted].[216] Dr. Kereiakes testified

[209] Bailey Day 6-PM 57:9-59:14.
[210] Bailey Day 6-PM 56:21-57:3.
[211] Bailey Day 6-PM 56:5-20.
[212] *See supra* § V; Kesselheim Day 4-PM 14:11-21.
[213] PX8000 Kesselheim ¶¶ 44-45; Kilcoyne Day 1-AM 98:25-99:9; Wood Day 2-AM 95:8-11; Pinto Day 3-PM 75:3-8.
[214] *See, e.g.*, Turco Day 4-AM 73:16-74:2 (referencing PX1049-010); PX1065, "Patient pool & revenue" sheet ("US AR market size & revenue"); PX1066-020-035; PX2461-003-005.
[215] Wood Day 2-AM 48:1-52:9; PX1267-006-09.
[216] Madrid Dep. 40:12-20; *see also* Castelli Dep. 141:9-14 [redacted]

that he was "surprised" that Edwards acquired the "only two valves . . . in clinical trial testing in the U.S. at this time," and noted that the FDA process is such that there only will "almost assuredly . . . be one or two valves in that space any time in the next . . . five to seven years."[217]

62. Dr. Wilson applied the HMT to determine the relevant geographic market for TAVR-AR devices and concluded that the United States is the appropriate geographic market.[218] American consumers can only access TAVR-AR devices that are approved for implantation by the FDA.[219] Even devices approved for commercial use outside the United States are not competitive for U.S. consumers unless the FDA approves them for U.S. clinical use.[220]

63. Defendants' expert, Dr. Bailey, agrees that the relevant geographic market for FDA-approved TAVR-AR devices would be the United States.[221] In particular, Dr. Bailey testified that Edwards and JenaValve engage in R&D activities targeted at the United States with the specific purpose of obtaining FDA approval.[222] Dr. Bailey also confirmed that an "international" TAVR system she identified as purported evidence of a broad innovation market was actually designed to address the requirements of middle and low income countries,[223] not the United States, and that she has seen no evidence that any foreign firms have plans to enter the U.S. market.[224]

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[217] Kereiakes Dep. 29:17-30:1, 30:10-30:25.
[218] Wilson Day 5-AM 26:2-24; PX8001 Wilson ¶¶ 51-52.
[219] Wilson Day 5-AM 26:2-27:5.
[220] PX8001 Wilson ¶ 51.
[221] Bailey Day 6-PM 59:11-14.
[222] Bailey Day 6-PM 33:19-34:1 ("Q. And you agree that the primary goal of TAVR-AR innovation for both Edwards and JenaValve is to achieve FDA approval for their TAVR-AR devices, right? A. Yeah. I would agree that both firms are seeking FDA PMA approval. I agrees [sic]. Q. They aren't simply innovating for the sake of innovating, right? A. No. I believe they are both seeking FDA PMA approval.").
[223] Bailey Day 6-PM 60:20-61:2.
[224] Bailey Day 6-PM 33:2-4.

VIII. The Proposed Transaction Tends to Create a Monopoly

A. Legal Standard

64. The Proposed Transaction tends to create a monopoly in TAVR-AR devices in violation of Section 7 of the Clayton Act. 15 U.S.C. § 18 (barring mergers "the effect [of which] . . . may . . . tend to create a monopoly"); *see United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 589 (1957) ("Section 7 is designed to arrest in its incipiency not only the substantial lessening of competition from [mergers], but also to arrest in their incipiency restraints or monopolies in a relevant market . . .").

65. Mergers to monopoly are unlawful regardless of whether they will substantially lessen competition (which they ordinarily do). *See du Pont*, 353 U.S. at 589-90; *Alliant*, 808 F.Supp. at 21. The words "may" and "tend" indicate that Congress declared illegal all mergers that move a firm "measurably closer" to monopoly, even if such movement does not arrive at a full monopoly. *See du Pont*, 353 U.S. at 592 (quoting *Transamerica Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 206 F.2d 163, 169 (3d Cir. 1953)); *see also Int'l Salt Co. v. United States*, 332 U.S. 392, 396 (1947) ("Under the law, agreements are forbidden which 'tend to create a monopoly,' and it is immaterial that the tendency is a creeping one rather than one that proceeds at full gallop; nor does the law await arrival at the goal before condemning the direction of the movement.").

66. Monopoly power has been defined to mean "the power to control prices or exclude competition," *Google*, 747 F.Supp.3d at 107 (quoting *du Pont*, 353 U.S. at 391), and courts can "infer the existence of monopoly power from a predominant share of the market," *Alliant,* 808 F.Supp. at 21 (citing *United States v. Grinnell,* 384 U.S. 563, 571 (1966)).

67. Courts have found market shares of 65 to 70% sufficient to establish monopoly power, *see FTC v. Meta Platforms, Inc.*, No. 20-3590, 2025 WL 3458822, at *39 (D.D.C. 2025)

(collecting cases); *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1206 (9th Cir. 1997) ("Courts generally require a 65% market share to establish a prima facie case of market power."), and this district found that a merger resulting in 100% market share "suggests a per se" violation of the Clayton Act, *Alliant*, 808 F.Supp. at 21. In *Alliant*, the merger combined two companies that were "the only two producers" of 120mm ammunition rounds and the only two developers of advanced tactical rounds "for the foreseeable future," who were competing for a multi-year Army contract. *Id.* at 20-21. The court found that a showing of a "complete monopoly" was "in itself . . . adequate for plaintiff to demonstrate a substantial likelihood that the merger will 'substantially . . . lessen competition or . . . tend to create a monopoly,' as prohibited by § 7 of the Clayton Act." *Id.* at 11-12.

68. Courts have applied Section 7's "tend to create a monopoly" clause to both vertical and horizontal mergers. *See du Pont*, 353 U.S. at 590-91 (vertical); *United States v. Bethlehem Steel Corp*, 168 F.Supp. 576, 585 (S.D.N.Y. 1958) (horizontal); *United States v. Pennzoil Co.*, 252 F.Supp. 962, 972 (W.D. Pa. 1965) (horizontal); *Alliant*, 808 F.Supp. 9 (horizontal).

B. The U.S. TAVR-AR Device Market Has Only Two Participants

69. Defendants acknowledge that J-Valve and Trilogy are the only two TAVR-AR devices in clinical trials in the United States and the only two devices to have been implanted in patients in the United States.[225] Leading physicians—including Defendants' witnesses—agree.[226]

70. Trilogy and J-Valve are both transfemoral TAVR devices with leaflet engaging mechanisms designed specifically to treat AR.[227] The two also offer similarly sized valves (66-

[225] Kilcoyne Day 1-PM 18:7-15; Sun Day 3-PM 44:2-5; Wood Day 2-AM 32:2-8.
[226] Vahl Day 4-AM 62:1-23; Kereiakes Dep. 29:17-22; PX6006-002; Chetcuti Day 6-AM 40:15-21.
[227] PX6006-002-003; Vahl Day 4-AM 60:15-17; McCabe Dep. 35:17-37:3.

90mm perimeters for Trilogy and 57-104mm for J-Valve)[228] that treat the vast majority of AR patients. With its current sizing portfolio, Trilogy can be used in approximately [redacted] of patients.[229] J-Valve can treat patients with larger annular perimeter sizes, but JenaValve is currently developing a larger size valve to treat those same patients.[230]

71. Both Trilogy and J-Valve are currently undergoing the rigorous and expensive FDA approval process that allows companies to sell their devices in the United States;[231] both have obtained FDA Breakthrough Device designation and received FDA approval for their EFS and, subsequently, their pivotal trials in dozens of sites across the United States.[232] Dr. Kesselheim and Dr. Bailey both estimate that devices at Trilogy and J-Valve's clinical stages are likely to obtain FDA approval (81% for devices at the PMA approval stage and 61% at the pivotal trial stage).[233] [redacted][234] [redacted][235]

72. Defendants' ordinary-course documents support a two-player TAVR-AR market. Internally, Edwards described acquiring both JenaValve and JC Medical as "hav[ing] a bakeoff" and deciding to "buy both" TAVR-AR pies.[236] A JenaValve executive's initial reaction to the news that Edwards bought both JC Medical and JenaValve was that "Edwards just bought the AR market" because Edwards bought the only two TAVR-AR devices in clinical trials in the United

[228] PX2190-009; s*ee also* McCabe Dep. 82:12-21.
[229] *See* Kilcoyne Day 1-AM 101:17-20; *see also* PX1394-003; Darmali Dep. 106:5-10; Wood Day 2-AM 48:8-49:10.
[230] *See infra* §§ X.C.1.
[231] *See supra* § V and *infra* § XI.A.2; Sun Day 3-PM 44:2-5; Vahl Day 4-AM 31:2-21.
[232] PX8000 Kesselheim ¶¶ 74-76; *see also* PX8001 Wilson Appendix A.
[233] PX8000 Kesselheim ¶ 66; DX0289 Bailey Exhibit 1.
[234] Kilcoyne Day 1-PM 85:3-13; Spadaro Dep. 145:24-146:17 (noting that FDA's deficiency letter has only delayed JenaValve's expected launch by one quarter).
[235] Sirimanne Day 5-PM 94:24-95:5; Kesselheim Day 4-PM 40:2-4.
[236] Wood Day 2-AM 36:24-37:6; PX1258 at 009; PX1262 at 072.

States.[237] In addition, JC Medical market share projections depict JC Medical and JenaValve splitting 100% of TAVR-AR market share through 2035, anticipating no other entrants.[238]

73. Other than Defendants, Laguna Tech is the only U.S.-based TAVR-AR developer.

[redacted][239]

[redacted].[240]

[redacted].[241]

[redacted].[242]

[redacted].[243]

74. Other than Edwards and JenaValve, none of the companies or devices identified by Defendants or their expert, Dr. Bailey, has conducted any clinical trials for TAVR-AR in the United States, and Defendants were unable to identify a single other company that has plans to initiate clinical trials for TAVR-AR in the United States.[244] For example, Mr. Kilcoyne was not aware of any U.S. offices, employees, or plans to conduct U.S. clinical trials among TAVR companies located outside the United States.[245]

75. In contrast to the lack of attention Defendants pay to Laguna Tech and foreign TAVR-

[237] PX2052-002; Sun Day 3-PM 59:12-15.
[238] PX1049-010; Turco Day 4-AM 73:16-75:10; *see also* PX1417.
[239] Keltjens Day 5-PM 31:23-32:6.
[240] Madrid Dep. 29:13-30:2, 125:22-126:1.
[241] Madrid Dep. 25:23-26:08; 27:06-27:10.
[242] Madrid Dep. 108:19-20, 108:22.
[243] Madrid Dep. 111:25-112:4, 113:16-18, 113:22-24, 116:1, 116:3-7, 116:9-25, 117:1-3, 117:5, 117:6-7, 117:9.
[244] *See, e.g.*, Bierman Day 3-AM 112:6-113:18 (referencing DX0197-015).
[245] Kilcoyne Day 1-PM at 16:6-18:4.

AR companies, the record is replete with examples of Defendants responding to competitive pressure from each other.[246] Initiating FDA-approved clinical trials is a significant step that signals to the market that the TAVR-AR device is not just a proof of concept. Receiving an IDE or breakthrough device designation indicates that a manufacturer intends to implant the valve in U.S. patients with the goal to commercialize the device in the United States.[247] Conversely, "[t]he mere fact that some company, someday may innovate a competing product" in the United States is too speculative to include that company in the U.S. TAVR-AR device market. *Illumina*, 88 F.4th at 1051. Simply publishing clinical data in medical journals and attending conferences in the United States without starting FDA-approved clinical trials is insufficient to affect the behavior of U.S. TAVR-AR manufacturers because those TAVR-AR valves are not current or foreseeable future options for U.S. patients.[248] As one Edwards executive testified, Laguna Tech is "an early-stage company that, you know, doesn't occupy a lot of Edwards' mind share at the moment."[249]

C. The Proposed Transaction Creates a Monopoly

76. The Proposed Transaction will create a monopoly that will likely persist for the foreseeable future. Edwards admits that JenaValve and JC Medical are the most advanced companies in the TAVR-AR space.[250] JC Medical projected that Trilogy and J-Valve would be the only TAVR-AR devices competing for market share through 2035.[251] Edwards executive Jeremy Bierman anticipates that, if Edwards owns JenaValve and JC Medical, for a period of

[246] *See infra* § X.
[247] *See supra* § V.
[248] *See infra* § XI.A.
[249] Lippis Dep. 52:17-53:4.
[250] Wood Day 2-AM 31:16-32:1 (referencing PX1001-001-02).
[251] PX1065-001.

time Edwards will be the only TAVR-AR player in the United States.[252] Defendants' industry expert, Dennis McWilliams, testified that he could not think of "a single example in U.S. history where a company had bought the two medical devices furthest along in the FDA approval pipeline."[253] No other potential entrant threatens to disrupt an Edwards' monopoly in the foreseeable future.[254]

77. Edwards' AR commercial strategy contemplates a durable monopoly and "durable leadership" "for a long time" with the "highest market share" in the TAVR-AR market with the ownership of both JenaValve and JC Medical.[255] With no alternative to surgery for AR patients, Edwards' due diligence on both companies noted that owning the only TAVR-AR devices in the United States would put it "in a situation where we are 'feeding the starving' so to speak."[256]

IX. The Proposed Transaction Is Presumptively Illegal

A. Legal Standard

78. The Proposed Transaction presumptively will substantially lessen competition by combining the only two participants in the TAVR-AR market. *See PNB*, 374 U.S. at 363; *Heinz*, 246 F.3d at 716. The resulting market share and concentration entails a presumption that the merger is illegal, and thus the FTC is entitled to a preliminary injunction unless Defendants carry their burden to rebut the presumption (which they cannot). *See PNB*, 374 U.S. at 363-64; *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F.Supp.3d 27, 62-66 (D.D.C. 2018).

79. Applying *PNB*, courts have held that "[b]y showing that the proposed transaction . . . will lead to undue concentration [in a particular market], the Commission establishes a

[252] Bierman Day 3-AM 84:12-18.
[253] McWilliams Day 6-AM 105:9-13.
[254] *See infra* § XI.A.
[255] Wood Day 2-AM 120:7-25 (referencing DX0160-028).
[256] Bierman Day 3-AM 83:14-19 (referencing PX1390-001).

presumption that the transaction will substantially lessen competition." *Staples*, 970 F.Supp. at 1083; *see also Heinz*, 246 F.3d at 715.

80. The Supreme Court held that a merger resulting in 30% market share and "undue concentration" triggers a presumption of unlawfulness. 374 U.S. at 364; *see also FTC v. Tapestry, Inc.*, 755 F.Supp.3d 386, 456-7 (S.D.N.Y. 2024); *IQVIA*, 710 F.Supp.3d at 378-79. Courts employ the Herfindahl-Hirschman Index ("HHI") to measure market concentration. *See*, *e.g.*, *United States v. Anthem*, 855 F.3d 345, 349 (D.C. Cir. 2017). HHI is calculated as the sum of the squares of each market participant's market share of. *See, e.g.*, *Tapestry*, 755 F.Supp.3d at 458. A merger is presumed anticompetitive if it increases the HHI by more than 100 points and results in a post-merger HHI exceeding 1,800 or a single firm with more than 30% market share. *Id.* at 458-59; Merger Guidelines § 2.1; *Heinz*, 246 F.3d at 716; *Chicago Bridge & Iron Co. NV v. FTC*, 534 F.3d 410, 431 (5th Cir. 2008).

81. The change in HHIs resulting from the Proposed Transaction—4,644 and 1,937 for clinical sites and TAVR-AR device units, respectively—far exceeds the 100 point threshold that establishes a presumption of illegality and is multiples greater than recent structural presumption cases. *See, e.g.*, *Bertelsmann*, 646 F.Supp.3d at 37 (enjoining merger where post-acquisition HHI of 3,111 and HHI increase of 891); *Tronox*, 332 F.Supp.3d at 207; *Heinz*, 246 F.3d at 716-17 (An HHI increase of 510 in a "highly concentrated industry" "creates, by a wide margin, a presumption that the merger will lessen competition.").

82. Several cases have applied the structural presumption where a defendant did not currently earn commercial revenue in the relevant market. In *Polypore*, the Eleventh Circuit applied the *PNB* presumption when a manufacturer of SLI battery separators, acquired a company that made a different kind of battery separator but was preparing to enter the SLI

battery separator market. 686 F.3d at 1213-1216. The 11th Circuit found that the FTC properly applied the *PNB* presumption because it was a "merger to duopoly." *Id.* at 1216. Likewise, the structural presumption has been applied where one defendant has exited the market but is likely to reenter. *Aetna*, 240 F.Supp.3d at 75-80, 90.

83. "The FTC need not present market shares and HHI estimates with the precision of a NASA scientist. The 'closest available approximation' will often do." *Sysco*, 113 F.Supp.3d at 54-55 (citation omitted); *see H&R Block*, 833 F.Supp.2d at 72 ("A reliable, reasonable, close approximation of relevant market share data is sufficient[.]"). "[P]recision in detail is less important than the accuracy of the broad picture presented." *Brown Shoe*, 370 U.S. at 341, n.69. Indeed, the D.C. Circuit affirmed a merger challenge in which the district court was "unable to calculate an HHI" in the relevant market, instead using a similar market as a proxy and noting the small number of competitors. *FTC v. PPG Industries, Inc.*, 798 F.2d 1500, 1504-06 (D.C. Cir. 1986). Here, with only two TAVR-AR devices in U.S. clinical trials, the increased concentration from two-to-one is plain—the FTC has shown the Proposed Transaction is presumptively illegal.

84. By establishing a merger is presumptively illegal, the government satisfies its prima facie case. *See United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990). The burden then shifts to Defendants to rebut the FTC's evidence. *Id.* at 983. "If the defendant successfully rebuts the presumption, the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Id.*

B. The Proposed Transaction Easily Meets the Standard for Presumptively Illegal Mergers

85. As discussed above in Sections VIII.B. and C., the U.S. TAVR-AR market has only two competitors in U.S. clinical trials. The Proposed Transaction will dramatically increase

concentration in the already highly concentrated U.S. TAVR-AR device market.[257] Dr. Wilson calculated HHIs[258] using data regarding U.S. TAVR-AR clinical sites and device implantations to assess pre- and post-merger market concentration.[259] His calculations show that the Proposed Transaction constitutes a merger to monopoly.[260] The HHIs based on clinical sites will increase from 5,356 to 10,000—a delta HHI of 4,644—and the HHIs based on units implanted will increase from 8,063 to 10,000—a delta HHI of 1,937.[261] Regardless of metric, the HHIs demonstrate a dramatic increase in concentration in the relevant market.[262]

X. The Proposed Transaction Eliminates Substantial Competition Between Edwards and JenaValve

A. Legal Standard

86. Where two merging parties are close competitors, the elimination of competition is itself an independent basis to conclude that the merger results in competitive harm, such as higher prices, reduced quality, and less innovation. *See United States v. Anthem, Inc.*, 236 F.Supp.3d 171, 216 (D.D.C. 2017); *Staples*, 970 F.Supp. at 1082-83 (finding competitive harm where the transaction "would eliminate significant head-to-head competition" between the merging parties); *Sysco*, 113 F.Supp.3d at 61 (collecting cases); *Heinz*, 246 F.3d at 717-719; *Aetna*, 240 F.Supp.3d at 43; *Bertelsmann*, 646 F.Supp.3d at 39; *H&R Block*, 833 F.Supp.2d at 79-81; Merger Guidelines § 2.2 ("Mergers can violate the law when they eliminate substantial competition between firms."). The evidence overwhelmingly demonstrates that Edwards and

[257] Wilson Day 5-AM 13:10-14:2, 31:3-24; PX8001 Wilson ¶¶ 61-65.
[258] Wilson Day 5-AM 29:24-31:24.
[259] Wilson Day 5-AM 13:10-14:2, 30:25-31:24; PX8001 Wilson ¶¶ 61-65.
[260] PX8001 Wilson ¶ 62, Figure 1.
[261] Wilson Day 5-AM 13:10-14:2, 30:25-31:24; PX8001 Wilson ¶¶ 62-64.
[262] Wilson Day 5-AM 13:10-14:2, 30:25-31:24; PX8001 Wilson ¶ 62.

JenaValve vigorously compete in the TAVR-AR device market today.[263]

87. When assessing head-to-head competition, "[c]ourts frequently rely on ordinary course documents and witness testimony illustrating that two merging parties view each other as strong competitors." *IQVIA*, 710 F.Supp.3d at 383; *see also Anthem*, 236 F.Supp.3d at 216 ("Relevant evidence of a merger's potential unilateral effects include the merging companies' ordinary course of business documents, testimony of industry participants, and the history of head-to-head competition between the two merging parties.").

88. Extensive evidence of head-to-head competition is "an important consideration when analyzing possible anti-competitive effects." *Anthem*, 236 F.Supp.3d at 216. The loss of this head-to-head competition shows both that consumers will have fewer options overall and fewer of the options they consider close substitutes. *Bertelsmann*, 646 F.Supp.3d at 39.

89. In addition, courts look to evidence of anticompetitive intent to "help[] us understand the likely effect of the monopolist's conduct." *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001); *see also Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) ("[K]nowledge of intent may help the court to interpret facts and to predict consequences."). As the Court previously held, "evidence that Edwards viewed JenaValve and JC Medical as competitors 'is likely to be highly probative evidence that the acquired firm[s] constituted . . . a threat,' which 'tends to show that the 'likely effect' of the acquisition [would be] to eliminate a threat to [the monopolist's] dominance.'" Mem. Op. Granting Pl.'s Mot. to Compel Disc. Resps. from Def. JenaValve Technology, Inc. 5, Dkt. No. 78 (citing *FTC v. Meta Platforms, Inc.*, 775

[263] Defendants' reference to the "potential competition" framework is a red herring. The potential competition framework applies when a firm acquires a *potential* entrant who *might* compete in the relevant market in the future but does not yet provide competitive pressure. *Yamaha Motor Co. v. FTC*, 657 F.2d 971, 980-981 (8th Cir. 1981). Defendants already compete in the TAVR-AR device market, so the potential competition framework is inapplicable.

F.Supp.3d 16, 59 (D.D.C. 2024)).

B. Defendants Are Viewed As Each Other's Most Significant Competitor

1. Edwards/JC Medical Views JenaValve as a Close Head-to-Head Competitor

90. JC Medical recognized JenaValve as its closest competitor in the United States. For example, its strategy documents describe JenaValve as "our closest competitor in USA TAVR-AR market."[264] When JC Medical sought an acquiror, it told investors that it and JenaValve were the "2 forerunners to bring a commercial transcatheter device to the USA market."[265]

91. Evidence from Edwards also indicates that JenaValve is a close competitor to JC Medical. Blessie Concepcion testified that a J-Valve in clinical trials [redacted] and confirmed that both devices' clinical studies also compete against each other.[266] Edwards' CEO, Mr. Zovighian testified that, should the transaction be blocked, [redacted][267] Mr. Zovighian went further, testifying that [redacted].[268] Therefore, Mr. Zovighian did [redacted].[269]

92. When JenaValve demanded a "strict firewall after they found out about [Edwards' acquisition of] JC Medical,"[270] Edwards' Laksen Sirimanne observed that it was "fair enough" that JenaValve wanted a firewall as "the deal hasn't closed yet and we have a competing AR

[264] PX1037-016.
[265] PX1048-020.
[266] Concepcion Day 3-PM 6:25-7:12 (referencing PX1299), 26:12-24.
[267] Zovighian Day 2-PM 78:18-79:5.
[268] Zovighian Day 2-PM 79:6-13; PX1437-001.
[269] Zovighian Day 2-PM 78:21-79:5; PX1437-001.
[270] PX1218-001; Sirimanne Day 5-PM 112:2-7.

technology."[271] Even Defendants' industry expert, Dennis McWilliams, agreed that "for Edwards's J-Valve, JenaValve's Trilogy device is the closest competitor for U.S. TAVR-AR."[272]

2. JenaValve Views Edwards/JC Medical as a Close Head-to-Head Competitor

93. The ordinary-course evidence demonstrates vigorous competitive interaction between Edwards and JenaValve, beginning when JC Medical received an IDE from the FDA and ramped up J-Valve's U.S. clinical activity.[273] JenaValve has continued to view J-Valve as Trilogy's "main competitor."[274] John Kilcoyne testified that JenaValve has tracked JC Medical's development of J-Valve from before Edwards' acquisition.[275] He explained that, as of the 2023 Cardiovascular Research Technologies (CRT) conference, JenaValve took JC Medical seriously, as they presented reasonably good data, were well capitalized, and had selected several strong principal investigators, including Dr. Kereiakes.[276]

94. JenaValve's ordinary-course documents, including numerous board presentations, routinely describe J-Valve as Trilogy's only competitor.[277] To limit the threat that J-Valve posed, JenaValve planned to inform clinical sites that they would be ineligible for Trilogy if they also implanted J-Valve.[278] Mr. Kilcoyne also viewed J-Valve's potential pivotal trial as a reason to "initiate ARTIST much sooner vs. later."[279] He also considered avoiding physicians he thought would prioritize J-Valve's clinical trials over a commercialized Trilogy valve.[280]

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[271] Sirimanne Day 5-PM 112:8-113:16; PX1235-001.
[272] McWilliams Day 6-AM 107:8-11.
[273] PX8001 Wilson App. A.
[274] PX3057-002.
[275] Kilcoyne Day 1-AM 94:25-94:9, 98:17-24; *see also* PX3057; PX2181; PX2231.
[276] Kilcoyne Day 1-AM 96:25-98:13; PX2181-002.
[277] Kilcoyne Day 1-AM 99:14-17, 101:21-102:1, 104:6-16, PX2186-024; PX2139-003-004.
[278] PX2069-002; *see also* PX2097-001.
[279] PX2074-002.
[280] PX2066-002.

95. In April 2024, JenaValve's Chief Medical Officer, Dr. Pinto, exchanged a series of emails with a JenaValve senior manager regarding competition with J-Valve. Dr. Pinto said "we are going to crush them" and, a few hours later, shared a YouTube clip from the 1982 film *Conan the Barbarian* in which the main character describes crushing his enemies.[281]

96. After JenaValve learned that Edwards had acquired J-Valve, [redacted].[282] JenaValve also raised concerns that, should the transaction close, J-Valve's sales would cannibalize sales of Trilogy and make JenaValve's earnouts more difficult to meet.[283]

3. Industry Participants View Edwards/JC Medical and JenaValve as Close Head-to-Head Competitors

97. Industry participants, including medical device strategics, view JC Medical and JenaValve as close head-to-head competitors. For example, Medtronic's Vice President of Business Development and Strategy for the Cardiovascular Portfolio, Gregory Larkin, identified [redacted].[284] Mr. Larkin went on to identify [redacted].[285]

[281] Pinto Day 3-PM 114:6-116:20 (referencing PX2119); PX2187.
[282] Keltjens Day 5-PM 29:18-30:3; PX1560-001; PX1218-001; PX1235-001.
[283] Kilcoyne Day 1-PM 32:3-17.
[284] Larkin Day 2-PM 42:8-16.
[285] Larkin Day 2-PM 42:17-25.

98. Laguna Tech [redacted].[286] Mr. Madrid [redacted].[287]

C. Competition Between the Defendants Benefits Consumers

1. Expanding Valve Sizes

99. JenaValve and Edwards compete to expand their valve size offerings to cover a broader range of patients. In March 2024, according to Mr. Kilcoyne, JC Medical was using their larger valve size TAVR-AR device to their advantage, as J-Valve could treat patients with perimeters up to 104 millimeters, while JenaValve was not able to treat patients with perimeters greater than 90 millimeters.[288]

100. That same month, in a presentation to its board, JenaValve made the case for "why large valve now," listing first that "competitor J-Valve already has a large valve size in portfolio," and summarized its reasoning: "it is imperative that [JenaValve] accelerate[s] the XL valve to be included in ARTIST to maintain [JenaValve's] leadership position."[289] In a draft of the same presentation, JenaValve discussed accelerating the Trilogy XL valve to proactively block J-Valve from commercial launch sites and eliminate J-Valve's competitive advantage.[290]

101. Two months later, in June 2024, Dr. Pinto told Mr. Kilcoyne that a JenaValve principal investigator was "worried J-Valve is gaining too much of a foothold" and didn't want to wait two years for a larger valve size for Trilogy.[291]

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[286] Madrid Dep. 40:12-15, 121:02-121:14.
[287] Madrid Dep. 40:16-20.
[288] Kilcoyne Day 1-AM 99:22-101:13.
[289] PX2186-024-025; *see also* PX2183-007.
[290] PX2342-024; *see also* PX2041-007.
[291] Pinto Day 3-PM 91:11-93:7 (referencing PX2132).

102. In August 2024, JenaValve continued to compare J-Valve and Trilogy's sizes noting: "To match J-valve offering, JVT needs to [sic] large valve size."[292] A year later, Edwards' Ms. Concepcion also wrote that [redacted].[293]

103. Even at the hearing, Dr. Pinto testified that JenaValve is still in the process of developing a larger valve size for Trilogy and plans to launch Trilogy XL in the future.[294]

2. Expanding Indications

104. JenaValve and Edwards also compete to cover a broader range of patient indications. JenaValve's ARTIST trial, if successful, would provide TAVR treatment options to patients with intermediate and low risk of surgery.[295] Patients, of any risk level, who are averse to invasive interventions like surgery may forgo treatment without a less invasive option such as TAVR.[296] Dr. Pinto testified that if successful, JenaValve's ARTIST trial would expand the approved indication for Trilogy so it would have a larger total addressable market.[297]

105. In March 2024, JenaValve pushed the board to move quickly on ARTIST because it "[p]revent[s] J-Valve overtaking JVT High Ground," "[s]lows J-Valve Enrollment," and "[b]locks J-Valve from JVT Site Penetration."[298]

106. JenaValve's Daniel Sun also testified that obtaining multiple indications for Trilogy, such as through ARTIST, would help JenaValve maintain market share dominance against J-Valve.[299] He wrote that the ARTIST trial allowed JenaValve to "extend [its] head start on J-Valve

[292] PX2190-009.
[293] PX1286-001.
[294] Pinto Day 3-PM 93:8-19; *see also* Keltjens Day 5-AM 123:8-25.
[295] Sharma Day 5-PM 151:7-152:10; *see also* Vahl Day 4-AM 66:3-67:3.
[296] Sharma Day 5-PM 129:15-130:15, 151:22-152:2; *see also* Vahl Day 4-AM 66:12-69:7.
[297] Pinto Day 3-PM 74:9-12; *see also* McCabe Dep. 76:7-21, PX2183-007.
[298] PX2186-023; *see also* PX2183-007.
[299] Sun Day 3-PM 53:23-54:1.

by moving on to low and intermediate risk as they work on their high-risk study."[300]

107. Additionally, Dr. Kereiakes, a principal investigator for both Defendants' clinical trials, encouraged both JC Medical and JenaValve to expand into treating patients with LVADs. He noted it would be beneficial to patients with dire unmet needs, expand the device-eligible population, generate revenue, "and put them on the playing field."[301] JenaValve started its LVAD registry in part to prevent J-Valve or any other competitor from usurping its TAVR-AR leadership.[302]

3. Speed to FDA Approval

108. Defendants' own documents and testimony confirm they vigorously compete to bring their devices more quickly to commercialization in the United States. [redacted].[303]

109. After the CRT Conference in February 2023, a JenaValve executive observed that "a major takeaway from CRT is that J-Valve is ramping up activities" on which they need to have "ongoing competitive intel" and that, while JenaValve has the "lead," they "will need to maintain it."[304] In particular, after hearing that JC Medical had notable principal investigators and had "already done 36 compassionate use cases in US," Mr. Sun wrote that J-Valve was "[c]oming hot" on JenaValve's heels.[305]

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[300] PX2041-007.
[301] Kereiakes Dep. 41:19-25, 42:23-43:8.
[302] Pinto Day 3-PM 101:19-105:3 (referencing PX2104).
[303] *See* Vahl Day 4-AM 46:13-20; *see also* Turco Day 4-AM 118:18-119:12 ("[O]nce we get beyond being that initial fast follower, we don't want to be that third, fourth, fifth to market.").
[304] PX2436-002.
[305] PX2417-003.

110. A few months later, in August 2023, J-Valve obtained breakthrough device designation from the FDA, to which a JenaValve executive responded, "Let the battle begin baby! A little competition is good!"[306] That same day, Mr. Sun commented, "Hopefully the leadership realizes its time to get ready for launch."[307]

111. In an October 2023 email, Dr. Turco wrote that J-Valve was working to "close the gap" between it and JenaValve.[308] Dr. Kereiakes, a principal investigator in both Defendants' clinical trials, sought to help JC Medical design a clinical protocol that would let it "leap-frog[]" JenaValve.[309] A few months later, in a February 2024 Strategic Planning presentation, JenaValve expressed concern over J-Valve's progress, referring to it as a "competitive threat,"[310] and highlighted that delaying the ARTIST trial risked losing clinical sites to J-Valve and losing "first-mover and 'leader' status."[311]

112. Similarly, in March 2024, JenaValve emphasized the importance of moving quickly on its ARTIST trial because "J-Valve is gaining momentum and poses a competitive threat with a newly completed EFS, an upcoming pivotal trial, and a credible roster of investigators."[312]

113. That same month, JenaValve's Director of Strategy and Field Operations emailed that "moving fast on the next trial for Trilogy will be of huge strategic importance to stay ahead of [J-Valve]. Let's go baby! Bring it on!"[313] Later that same month, JenaValve's Chairman of the Board suggested to JenaValve's CEO to "[r]un the ARTIST IDE study asap."[314]

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[306] PX2480-002.
[307] PX2533-002.
[308] PX1038-001; *see also* PX1176.
[309] PX1187; Kereiakes Dep. 68:10-14.
[310] PX2298-005.
[311] PX2298-009.
[312] PX2322-005.
[313] PX2042-001.
[314] PX2381-001.

114. Edwards has continued to focus on accelerating J-Valve since the FTC lawsuit was filed, with Edwards' CEO instructing the team to make J-Valve go faster.[315] He considered it "[his] duty as CEO" to do anything possible with JC Medical.[316] Edwards' Ms. Concepcion testified she understood that the FTC's lawsuit "highlighted the urgency" to re-start J-Valve's clinical trials.[317] Following through on their CEO's orders, Edwards leadership scheduled a meeting in August 2025 "specifically on how we can accelerate Sojourn."[318]

115. At the hearing, Mr. Sun testified that he often used J-Valve to incentivize others to pursue projects like the ARTIST trial and the Trilogy large valve program; he "would bring up J-Valve and say, look, they are doing things, they are moving things along, we should do that," and he used J-Valve as a reason to "move faster" on these projects.[319]

116. If the Proposed Transaction does not close, Edwards will be asking itself how best to accelerate JC Medical's plans, move as quickly as possible to commercialize its own TAVR-AR device and "close the gap on any time lost."[320] Larry Wood, Edwards' former TAVR President, wrote that during the pendency of the FTC's investigation, "with the drama around Jena, it is super critical we move [the JOURNEY] trial as quickly as we safely can."[321]

4. Better Clinical Outcomes

117. JenaValve and JC Medical also compete to obtain better clinical outcomes for their respective devices. In a May 2023 email to the JenaValve CEO, Dr. Pinto provided 18 bullets on the "clinical outcomes" from J-Valve's EFS results and how JenaValve needs "to continue to

[315] Zovighian Day 2-PM 45:2-21; Bierman Day 3-AM 86:23-87:8; PX1389-001; PX1437-001.
[316] Zovighian Day 2-PM 45:22-46:6.
[317] Concepcion Day 3-PM 13:21023, 14:21-15:2; *see also* PX1528-002.
[318] PX1285-003; *see also* PX1389-001; Bierman Day 3-AM 86:23-87:8.
[319] Sun Day 3-PM 50:1-21; *see also* PX2196-002-03.
[320] Bierman Day 3-AM 86:7-18; PX1016 at 001; *see also* PX1489-014.
[321] PX1263-001.

streamline the procedure."[322] A few months later, Dr. Pinto emailed the JenaValve board a paper in which JenaValve's Trilogy data compared favorably against JC Medical's J-Valve data.[323]

118. In turn, JC Medical analyzed Trilogy's clinical data and concluded that J-Valve's "clinical performance has to match or be superior to JenaValve's"[324] and "[w]e need to start US pivotal trial before Trilogy is approved."[325]

119. After the 2023 Transcatheter Cardiovascular Therapeutic (TCT) Conference, JC Medical's CEO wrote about "[g]reat excitement around our valve and the opportunity for improvement from Jena[Valve]" including better "[p]acer rates," "[l]arger [a]nnular dimensions," "[e]ase of use," and "[n]o need for general anesthesia."[326] Likewise in 2025, Edwards' Ms. Concepcion wrote that J-Valve "may have edge" on valve migration against Trilogy to which her Edwards colleague responded, "Fingers crossed. That comparison will probably be best with the data side by side, though."[327]

5. Clinical Sites

120. Competition between J-Valve and Trilogy has spurred aggressive clinical site expansion that would not have existed but for the threat of competition. [redacted]"[328]

[322] Pinto Day 3-PM 77:13-78:9 (referencing PX2195).
[323] Pinto Day 3-PM 83:9-84:6, 85:24-87:15 (referencing PX2109).
[324] PX1037-016.
[325] PX1037-016.
[326] PX1036-001.
[327] PX1289-002.
[328] Larkin Day 2-AM 129:8-130:1; *see also* Kereiakes Dep. 64:9-11, 13-16, 64:18-65:8.

121. Most principal investigators work with one company or the other, but rarely both.[329] Having "two competing trials of the same protocol or similar" at a clinical site would "cannibalize each other" because there would not be enough patients "to enroll at any reasonable pace."[330] [redacted]," and, as Dr. McCabe noted, seek to reach the best clinical sites that would allow them to enroll quickly and execute the trial expertly.[331] Evidence shows that J-Valve was competing with JenaValve for the same clinical trial sites.[332]

122. JenaValve sought to accelerate its ARTIST trial because of competition from JC Medical at clinical sites, with Dr. Pinto writing in November 2023 that "it is time critical and mission critical to get our ARTIST Sites buttoned up ASAP (Concern about Jvalve)."[333] According to Dr. Pinto, JenaValve streamlined its patient enrollment process in part because of principal investigator concerns that patients would "jump to J-Valve."[334]

123. After learning Edwards' JOURNEY would start re-enrolling patients in March 2025, JenaValve's Mr. Sun proposed that JenaValve launch ARTIST and commercialize Trilogy at all JOURNEY trial sites to get physicians to prioritize Trilogy over J-Valve.[335]

6. Price Competition

124. Both Edwards and JenaValve charge hospitals for their TAVR-AR devices used in clinical trials.[336] Evidence shows that the two compete on cost. For example, JC Medical did not

[329] McCabe Dep. 67:18-68:10.
[330] Spadaro IH 151:21-152:17.
[331] Larkin Day 2-AM 129:8-130:1; McCabe Dep. 74:9-12, 74:14-75:6.
[332] Spadaro IH 90:18-20, 91:10-12; 92:10-13.
[333] PX2104-001; Pinto Day 3-PM 105:4-106:6 (referencing PX2104).
[334] Pinto Day 3-PM 93:20-97:3 (referencing PX2132).
[335] PX2283-003.
[336] Kereiakes Dep. 32:7-10, 32:19-22 (JenaValve also charges sites for valves used in the continued access program), 33:11-14.

charge The Christ Hospital for J-Valve devices used in clinical trial and compassionate use cases, but the hospital had to resume paying for the device after Edwards acquired JC Medical.[337]

125. The Christ Hospital experienced significant benefits from the lower price that JC Medical initially charged—it did not have to cap enrollment in the JOURNEY trial and could afford to treat many more patients.[338] [redacted].[339] [redacted].[340]

126. Dr. Kereiakes of The Christ Hospital expressed concern about pricing if both devices were owned by Edwards, noting if one company "can set the price, I'm not sure we can participate [in the clinical trial]. And if we're forced to participate, it's a challenge."[341] Dr. Kereiakes confirmed that, in clinical trials, where patients are eligible for either valve, the hospital "would use the valve that costs less to get the job done."[342] Ultimately, The Christ Hospital declined to pay for Trilogy valves to participate in JenaValve's clinical trials because it had other options, namely J-Valve, for its patients suffering from AR.[343]

127. Price competition between JenaValve and Edwards will continue even after Trilogy receives PMA approval before J-Valve. For example, JenaValve's Mr. Sun proposed pricing rebates on a commercialized Trilogy device "in an effort to get [JOURNEY sites] to prioritize

[337] Kereiakes Dep. 33:11-34:1, 48:6-17
[338] Kereiakes Dep. 37:17-38:5, 38:10-20.
[339] Kereiakes Dep. 15:2-16:7, 16:16-17:5.
[340] Kereiakes Dep. 34:23-35:1, 35:9-22.
[341] Kereiakes Dep. 94:22-24, 95:2-7.
[342] Kereiakes Dep. 98:5-11, 98:14-20.
[343] PX2232; Kereiakes Dep. 56:11-20, 57:14-19, 57:20-58:16, 58:24-59:8; Pinto Day 4-AM 10:4-12:1 (referencing PX2201); s*ee also* Concepcion Day 3-PM 8:23-9:7 (referencing PX1604).

Trilogy implants over J-Valve."[344] [redacted]

[redacted].[345]

128. Defendants also anticipate that JenaValve and J-Valve will compete on price once both are commercialized. [346] For example, JenaValve plans to increase the list price of Trilogy upon launch because JenaValve would have the only TAVR-AR device approved commercially in the United States.[347] But JenaValve estimates that J-Valve's entry into the commercial market will erode JenaValve's market share "15 to 20 percent."[348]

129. Edwards similarly contemplated a premium pricing strategy for JenaValve and JC Medical anticipating that they would be "first to market" and would "have one shot at setting the bar on commercial price" because it knows that "once the bar is set, it is really hard to raise it."[349] Edwards' diligence on both JenaValve and JC Medical anticipated the same average sales price (ASP) post commercialization.[350] By owning JenaValve and JC Medical, Edwards anticipates not having to deal with "low-cost TAVR-AR alternatives" for "a period of time."[351]

7. Patient Choice

130. Multiple TAVR-AR devices provide physicians options to better serve individual patients. JenaValve's CEO wrote that "having another player in the [AR] space is a net positive . . . for this underserved patient population."[352] He agreed that sometimes customers need multiple valves to treat different pathologies.[353] If Edwards decides to discontinue either

[344] PX2414-002.
[345] Vahl Day 4-AM 44:8-45:14.
[346] Spadaro IH 182:2-9, 183:1-21, 194:1-5 (referencing PX2090); *see also* PX2530-003.
[347] Kilcoyne Day 1-AM 93:20-94:6.
[348] Spadaro IH 182:2-3, 8-9, 183:1-5, 8-21 (referencing PX2090); *see also* PX2356-003.
[349] PX1390-002.
[350] PX1453-001, 003, 005, 007, 009.
[351] PX1390-002; Bierman Day 3-AM 84:19-85:2.
[352] PX2182-001.
[353] Kilcoyne Day 1-AM 104:23-25.

Trilogy or J-Valve—discussed at Section X.D—doctors would lose the ability to choose the device that best suits a patient's anatomy.

131. [redacted].[354] There will be no back-up option if Edwards opts for a single device and experiences any interruption in supply.

D. Edwards' Plans Show That the Proposed Transaction Is Harmful

132. The Proposed Transaction's harms are not speculative or theoretical. Rather, documents and testimony show that, unlike JenaValve, Edwards plans [redacted], has no commitment to pursue larger Trilogy valves, and would stop developing whichever valve it finds less appealing.

133. [redacted].[355] [redacted].[356] [redacted].[357]

1. The Proposed Transaction Has Delayed ARTIST

134. The Proposed Transaction has already delayed JenaValve's ARTIST trial and, if it closes, further delays are likely. ARTIST is a clinical trial to expand Trilogy's indications, in part due to competition with J-Valve, as explained above in X.C.2. Multiple witnesses and exhibits demonstrate that, immediately after executing the JenaValve merger agreement, [redacted]

[354] Vahl Day 4-AM 43:12-44:7.
[355] Zovighian Day 2-PM 78:11-13.
[356] Zovighian Day 2-PM 78:14-17; PX1437-001.
[357] Zovighian Day 2-PM 78:18-20.

[redacted].[358] Even prior to closing, Edwards wanted to tell JenaValve to stop ARTIST.[359] [redacted].[360] In contrast, if the Proposed Transaction terminates, JenaValve expects a "full ARTIST launch."[361]

2. Edwards Likely Will Stop Development of Larger Trilogy Valves

135. As discussed above in X.C.1, JenaValve is pursuing larger valve sizes to compete against J-Valve's largest valve size. Edwards' Vice President of Strategy testified that Edwards has not determined whether it will continue JenaValve's large valve program, and Mr. Bobo indicated that Edwards would not undertake the project.[362] Further, Dr. Bailey assumed Edwards would not develop larger Trilogy valve sizes when she testified that J-Valve's larger sizes give Edwards an incentive to continue developing J-Valve even if it also owns Trilogy.[363] By contrast, if the deal terminates, JenaValve plans significant effort on larger Trilogy valves.[364]

3. The Proposed Transaction Likely Will End Development of Trilogy or J-Valve

136. Edwards is likely to commit to one platform—J-Valve or Trilogy—and drop the other over time, and the evidence indicates Edwards expects J-Valve to supplant Trilogy. Notably, multiple JenaValve employees have predicted that Edwards will ultimately "kill" one of the programs.[365] Edwards is unlikely to incur the cost of maintaining and developing two

[358] *See, e.g.*, PX1280-001; Concepcion Day 3-PM 12:6-12; PX1512-001; Sharma Day 5-PM 145:13-146:4, 147:16-21.
[359] PX1192-001.
[360] Kilcoyne Day 1-PM 55:6-9, 56:4-12, 58:20-59:4; *see also* PX2380-002; PX2311-002; PX2397-003; Keltjens Day 5-PM 25:1-5, 25:14-27:9; PX2398-001 [redacted]
[361] PX2323-012; *see also* Kilcoyne Day 1-AM 115:19-117:14.
[362] Bierman Day 3-AM 87:23-88:1; Bobo Day 3-AM 33:9-23.
[363] Bailey Day 6-PM 67:9-13.
[364] Kilcoyne Day 1-AM at 115:19-24; Kilcoyne Day 1-PM 4:19-5:1.
[365] PX2062-002; *see also* Sun Day 3-PM 61:22-62:4; PX2053-002; and PX2432-002.

platforms given its J-Valve valuation model assumes that J-Valve could treat all TAVR-AR patients,[366] while Trilogy treats [redacted] of patients.[367] Edwards discontinued CENTERA in part because of the time and resources required to match the performance of its SAPIEN device.[368]

137. Indeed, Edwards' plans show it expects J-Valve to be its long-run platform. Edwards' Mr. Wood for instance told Edwards' CEO that "feedback from the doctors who have used Jena and [J-Valve] is that [J-Valve] is clearly the better platform."[369] Following Edwards' agreements to acquire JC Medical and JenaValve, Edwards' Vice President of Strategy circulated materials for a leadership meeting that described Trilogy as Gen 1 and J-Valve as Gen 2.[370] A key priority discussed at that leadership meeting was launching JenaValve as the "Gen 1" device and then proceeding with J-Valve as "Gen 2" over JenaValve. [371] [redacted], and an October 2024 presentation suggests that Edwards may "ramp down Jena [and] to ramp up JC."[372] To date, Edwards has spent eighteen months on future J-Valve iterations without access to JenaValve technology.[373]

E. Economic Analysis Confirms the Proposed Transaction Likely Results in Higher Prices, Decreased Patient Access, and Reduced Innovation

138. Dr. Wilson concluded that the elimination of competition between Edwards and JenaValve was likely to lead to increased pricing and decreased patient access.[374] Dr. Wilson explained that economic theory predicts upward pricing pressure, which can reduce patient

[366] Bailey Day 6-PM 63:7-13.
[367] DX0289 Bailey ¶ 77; *see also* Bailey Day 6-PM 64:20-65:4; Kilcoyne Day 1-AM 101:17-20.
[368] Bailey Day 6-PM 71:8-12.
[369] PX1272-002; *see also* Wood Day 2-AM 38:4-16.
[370] PX1394-003; *see also* Bierman Day 3-AM 76:23-77:2.
[371] Concepcion Day 3-PM 9:18-20, 12:13-18; PX1280-001.
[372] PX1302-025; PX1279-003; *see also* Concepcion Day 3-PM 24:16-21; PX1311-001 ("The resistance from R&D to make updates to the JC Medical design / process needs to be tempered a bit. In actuality, this IS a 2.0 for the supply chain. Jena Valve will be version 1.").
[373] Wood Day 2-AM 52:21-53:10.
[374] Wilson Day 5-AM 33:13-34:9, 37:8-41:2.

access, when companies are close competitors, and that the record here is consistent with those predictions, notwithstanding that companies in clinical trials are focused on long-run value rather than contemporaneous profits.[375] As a comparator, Dr. Wilson examined the TAVR-AS market and determined that the existence of Medtronic and other competitors caused Edwards to offer pricing rebates even prior to Medtronic receiving FDA approval.[376] Dr. Wilson and Dr. Bailey agree that pre-commercial devices can put competitive pressure on FDA-approved devices.[377]

139. Further, Dr. Wilson concluded that the elimination of competition between Edwards and JenaValve was likely to reduce innovation. In addition to the general association between monopolies and reduced innovation, Dr. Wilson considered indicia identified in the economic literature as associated with innovation-enhancing mergers.[378] He concluded that the Proposed Transaction is likely to reduce innovation because it combines two companies vying for future sales, and no countervailing indicia are present.[379] In addition, Dr. Wilson analyzed the drivers of innovation in the analogous TAVR-AS market and concluded that competition from Medtronic and other TAVR-AS device manufacturers spurred Edwards to innovate.[380]

XI. Defendants Cannot Rebut the FTC's Prima Facie Case

140. To the extent the Court considers the rebuttable bases for the illegality of the Proposed Transaction (structural presumption and elimination of substantial competition), "[t]he burden of producing evidence to rebut [the prima facie case] then shifts to the defendant." *Baker*

[375] Wilson Day 5-AM 39:6-41:2; PX8001 Wilson ¶¶ 113-117.
[376] Wilson Day 5-AM 39:6-41: 21; *see also* PX1276-007.
[377] PX8005 Wilson Reply ¶ 6 ("Dr. Bailey states that '. . . a firm does not need to enter into commercialized TAVR-AR device sales in order to be capable of providing competitive pressure.' This is consistent with my characterization of the pre-commercialization competition between Edwards and JenaValve.") (quoting DX0289 Bailey ¶ 55).
[378] Wilson Day 5-AM 34:10-35:18, 41:22-50:1; PX8001 Wilson ¶¶ 86-105.
[379] Wilson Day 5-AM 41:22-47:11; PX8001 Wilson ¶¶ 86-105.
[380] Wilson Day 5-AM 48:16-50:1; PX8001 Wilson ¶¶ 106-108.

Hughes, 908 F.2d at 982. "The more compelling the prima facie case, the more evidence the defendant must present to rebut it successfully." *Id*. at 991.

141. "Allegations that competition is not in the best interest of the [public] or an industry are not new to the courts," and do not insulate an anticompetitive merger from searching review. *Alliant*, 808 F.Supp. at 23. The plain language of Section 7, standard economic theory, Defendants' documents, and common sense all agree the best way to bring live-saving TAVR-AR devices to the most Americans at the lowest price point and at the highest quality is through competition. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 104 n.27 (1984) ("[T]he unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress. . . ."). The Supreme Court rejected companies' benevolent monopolist arguments that would convert trials into extended examinations of their bona fides to win exceptions to competition law. *See, e.g.*, *Nat'l Soc'y of Pro. Eng'rs v. United States*, 435 U.S. 679, 695-96 (1978) ("The judiciary cannot indirectly protect the public against [alleged societal] harm by conferring monopoly privileges on" defendants.).

142. Courts have scrutinized "fortune-telling and hollow promises from company executives" of merging firms as "self-interested" and "self-serving statements." *Tapestry*, 755 F.Supp.3d at 484-85. Here, the promises from Edwards' witnesses lack the concrete, verifiable, and merger-specific evidence that courts require in antitrust cases.[381]

381 [redacted] *See infra* § XI.D.7.

A. Entry or Expansion Are Unlikely to Be Timely, Likely, or Sufficient to Counteract the Anticompetitive Effects of the Proposed Transaction

1. Legal Standard

143. Defendants bear the burden of showing that "low barriers to entry" rebut Plaintiff's prima facie case. *Bazaarvoice*, 2014 WL 203966, at *71; *see also Heinz*, 246 F.3d at 715 n.7. To meet their burden, Defendants must demonstrate that any entry by new firms, or expansion by existing firms, will be "timely, likely and sufficient in its magnitude, character, and scope" to counteract the Proposed Transaction's anticompetitive effects. *Anthem*, 236 F.Supp.3d at 222 (quoting *H&R Block*, 833 F.Supp.2d at 73); *see also IQVIA*, 710 F.Supp.3d at 393-95 (rejecting the argument that the "mere threat of entry into the market or expansion by existing firms is enough to provide a competitive constraint and rebut the FTC's prima facie case").

144. "The mere existence of potential entrants does not by itself rebut the anti-competitive nature of an acquisition." *Chicago Bridge*, 534 F.3d at 436. Entry must be "of a sufficient scale to compete on the same playing field," *id.* at 430, and Defendants must demonstrate that entry will be "sufficient to fill the competitive void" that will result from the merger. *H&R Block*, 833 F.Supp.2d at 73; *see also Aetna*, 240 F.Supp.3d at 52-53; *Bertelsmann*, 646 F.Supp.3d at 53 (timeframe for entry analysis is no longer than "two to three years"). Entry also must occur before the merger causes anticompetitive effects and must maintain competition over the long term. *Aetna*, 240 F.Supp.3d at 52-53. Defendants cannot make that showing here.

145. Given the high barriers to entry for new TAVR-AR devices, even if a new entrant were to arrive in the relevant market imminently, the monopoly-level concentration levels presented by this merger are prohibited in the D.C. Circuit: "As far as [the D.C. Circuit] can determine, no court has ever approved a merger to duopoly" that eliminates head-to-head competition in a market with high barriers to entry. *Heinz*, 246 F.3d at 717; *see Whole Foods*,

548 F.3d at 1043 (Tatel, J., concurring) "([T]here can be little doubt that the acquisition of the second largest firm in the market by the largest firm in the market will tend to harm competition in that market."); *Alliant*, 808 F.Supp at 21 ("[P]laintiff's showing of the creation of a 100 percent monopoly . . . and the barrier to future entry alone suggest a *per se* violation of the Clayton Act justifying plaintiff's preliminary relief.").

2. Defendants Fail to Rebut That Significant Barriers to Entry Exist

146. Executives from both Edwards and JenaValve agree that TAVR-AR devices supplied to American patients must meet the FDA's standards. JenaValve's Dr. Pinto testified that "you can't just have a new valve and then start putting it into people" as the FDA requires data to support its efficacy and safety before it could be implanted in humans.[382] Edwards' Mr. Zovighian testified that the FDA sets a high clinical bar to ensure that American patients do not get suboptimal technologies.[383] The FDA approval process, beginning with the IDE application, presents a time-and resource-intensive barrier to entry.[384]

147. The FDA is "very skeptical of data of high-risk devices that comes from outside the United States because that data might not be generalizable to U.S. patients," and ex-U.S. data rarely forms the sole basis of approval for the FDA approval of high-risk devices.[385] Out of the approximately two dozen high-risk devices approved in the past year, only one PMA application was approved based solely on ex-U.S. clinical data.[386] Of the original PMA approvals of TAVR-AS devices, none was approved solely on the basis of ex-U.S. data.[387] Medtronic's CoreValve

[382] Pinto Day 4-AM 8:11-24.
[383] Zovighian Day 2-PM 71:13-17.
[384] *See supra* § V; *see also* PX8000 Kesselheim ¶¶ 59-65.
[385] Kesselheim Day 4-PM 12:24-13:2, 29:15-30:5, 34:2-17; *see also* PX8000 Kesselheim ¶¶ 89-90.
[386] Kesselheim Day 4-PM 35:6-17; PX8000 Kesselheim App. D, Ex. B.
[387] Kesselheim Day 4-PM 13:16-24.

received PMA approval based solely on U.S. data, even though it had European approval prior to Medtronic's acquisition.[388] None used pivotal trial or supplemental data from China.[389]

148. Likewise, JenaValve's Trilogy conducted European clinical trials to obtain its CE Mark, but still based its FDA submission for PMA approval solely on American patient data [redacted]."[390]

149. "In nearly all cases, high-risk medical devices are approved by the FDA based primarily on data collected in the United States."[391] When ex-U.S. data is used in support of a PMA application, it is often supplemental or secondary to data collected in the United States.[392]

150. When the FDA evaluates ex-U.S. data, the principles regarding the validity, reliability, and generalizability of the data to the United States, along with the quality of the collection of the data and the data itself, are the same at any stage of the FDA approval process.[393] And while foreign data could theoretically be used to support an IDE application (i.e. to support a request for a U.S. feasibility or pivotal study), the same FDA regulatory requirements apply to study data in support of an IDE, and the FDA would be "similarly skeptical" of such foreign-collected data.[394]

151. "[F]oreign data may not be accepted by the FDA if there were problems in the way that they were collected or if there were any irregularities."[395] Manufacturers are required to meet the FDA's regulatory requirements before their ex-U.S. data would be accepted by the FDA

[388] Kesselheim Day 4-PM 89:4-14, 89:18-90:10; PX8000 Kesselheim ¶ 113, Table 5.
[389] Kesselheim Day 4-PM 90:11-15.
[390] Keltjens Day 5-PM 32:7-16.
[391] Kesselheim Day 4-PM 12:24-13:7; *see also id.* 29:15-30:5, 34:2-19.
[392] Kesselheim Day 4-PM 12:24-13:7, 29:15-30:5; *see* Madrid Dep. 48:4-14.
[393] Kesselheim Day 4-PM 90:19-91:12.
[394] Kesselheim Day 4-PM 34:20-36:1.
[395] Kesselheim Day 4-PM 34:20-35:5.

to support an IDE for a clinical trial.[396]

152. "[I]n general, high-risk medical device manufacturers will need U.S. data as the primary basis for approval of their high-risk medical devices," and it is likely that any TAVR-AR device currently in development outside of the United States will first need to obtain an IDE in order to begin gathering U.S. clinical data.[397] As Dr. Chetcuti testified, for a valve with only foreign data, he would still "expect and demand that there would be a U.S. study to collaborate [sic] what the outside data suggests" and further attested that he would not implant a valve in a patient if it was only in clinical trials in another country but not in clinical trials in the United States.[398]

153. Intellectual property protections covering TAVR-AR technologies may also present a significant barrier to entry. Defendants' industry expert Dennis McWilliams testified that intellectual property protections can be a substantial barrier to entry for Class III medical devices, and that the combined JC Medical and JenaValve patent portfolios could potentially block any firm from entering the U.S. TAVR-AR market.[399] Likewise, [redacted] "[400] And Edwards itself explained acquiring both devices because "it would be very difficult to build a best-in-class AR technology without violating their patents."[401]

[396] Kesselheim Day 4-PM 36:14-24; *see also* PX8000 Kesselheim ¶¶ 89-90.
[397] Kesselheim Day 4-PM 30:13-24, 31:9-14; *see also* PX8000 Kesselheim ¶ 95.
[398] Chetcuti Day 6-AM 23:11-21; 40:22-25.
[399] McWilliams Day 6-AM 109:4-6, 114:13-115:6.
[400] Madrid Dep. 139:1-8.
[401] PX1390-006.

3. Evidence Shows That Entry, if Any, by Any Other TAVR-AR Device Currently in Development Will Not Be Timely, Likely, or Sufficient

154. Other than Defendants, no alleged TAVR-AR competitor was called to testify live at trial.

155. Other than Trilogy and J-Valve, no TAVR-AR device is currently in clinical development in the United States.[402] No witness, including Defendants' executives and experts, has identified any other TAVR-AR device currently in clinical development in the United States.[403] In fact, Defendants own self-serving, made-for-litigation TAVR-AR competitive landscape shows that aside from Edwards only JenaValve has a TAVR-AR U.S. clinical study.[404]

156. There is no evidence of any plan to pursue FDA clinical trials for any TAVR-AR device currently in clinical development outside of the United States.[405] In fact, no other TAVR-AR device company has even taken the first step towards FDA approval.[406] In March 2024, for example, JenaValve described TAVR-AR devices other than JC Medical, as being in "early clinical stages" and five-plus years from U.S. commercialization.[407]

157. Likewise, Dr. Chetcuti testified that he is aware of one Chinese device called Hanchor Valve but conceded during direct examination by the Defendants that he "ha[s] not seen them have any interest yet in the U.S." and on further questioning from Plaintiff confirmed he is not "aware of a forthcoming U.S. clinical trial."[408] Other Chinese companies are similarly

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[402] Kesselheim Day 4-PM 33:11-16.
[403] *See, e.g.*, Wood Day 2-AM 32:2-32:8; Sun Day 3-PM 43:8-10; 44:2-5; Kilcoyne Day 1-PM 18:7-15; Vahl Day 4-AM 63:3-63:6; Chetcuti Day 6-AM 40:15-40:21; McWilliams Day 6-AM 104:8-14); Bailey Day 6-PM 32:23-33:1; *see also* Larkin Day 2-PM 42:21-25 [redacted]
[404] DX0289 (Bailey Report) Exhibit 28; DX0197-15; DX0149-5-8.
[405] Kesselheim Day 4-PM 92:23-93:1.
[406] Kesselheim Day 4-PM 33:7-10.
[407] PX2413-0015.
[408] Chetcuti Day 6-AM 20:14-21:1; 41:7-13; 41:4-6.

situated. Jenscare, for example, has not begun either an EFS or a pivotal study in the United States.[409]

158. In addition, although an Edwards' strategy executive notes that "[t]he only potential entrant in US/EU would be Laguna Tech,"[410] as explained in Section VIII.B there is no indication that [redacted].[411]

159. As Dr. Kesselheim explained, unlike meaningful engagement with the FDA regulatory process, appearing at a medical conference does not provide a reliable indication that a company plans to develop a device in the United States.[412] Manufacturers may present any stage of research at conferences like the 2025 TCT Conference, and Dr. Kesselheim did not consider attendance at such conferences to be evidence of any intention to begin U.S. clinical trials.[413] For example, the TAVR-AR device manufacturers listed by Defendants as attendees at medical conferences include companies that have only implanted TAVR-AR devices in animals or are designing TAVR-AR devices specifically for countries other than the United States.[414]

160. If any TAVR-AR device currently in development outside of the United States were to begin seeking FDA approval, they would need U.S. clinical data, and thus would need to obtain IDE approval before beginning U.S. clinical testing of their device.[415] By regulation, the FDA has up to 30-days to review an IDE application; however, the process can take much longer

[409] Bierman Day 3-AM 112:25-113:11.
[410] PX1634-002.
[411] Keltjens Day 5-PM 31:23-32:6.
[412] PX8004 Kesselheim Reply ¶ 32.
[413] PX8004 Kesselheim Reply ¶ 32.
[414] Bailey Day 6-PM 60:13-62:13.
[415] *See supra* § XI.A.2; Kesselheim Day 4-PM 18:1-16, 33:20-36:1; *see also* Madrid Dep. 48:4-14 [redacted].

if the FDA has questions or concerns about an application.[416] For example, it ultimately took four years for J-Valve to receive an IDE for its EFS.[417]

161. The majority of TAVR-AR devices identified by Defendants are in development in China.[418] Evidence shows that Chinese clinical data may not meet the FDA's rigorous standards, and Mr. Zovighian testified that he is not aware of any Chinese company that would have the clinical data to satisfy the FDA process.[419] As a comparative example, no TAVR-AS device used data from China in support of its PMA approval.[420]

162. Mr. Zovighian also expressed concern that clinical studies and devices approved in China are not at the same level of scientific rigor as those in the United States, and that Chinese companies offering TAVR technology may be cutting corners and killing people.[421] For example, earlier this year, a patient tragically died while undergoing a procedure using a Chinese device during a live transmission shown to thousands of physicians during a medical conference.[422]

163. Even if a new entrant decided to pursue the FDA approval process and was able to secure an IDE, evidence shows that it would be at least five years behind both Trilogy and J-Valve. Overall, it can take from 5 to 10 years, and on average 8.5 years, for a high-risk device to go from IDE approval to PMA approval.[423] Dr. Kesselheim testified that the average 8.5 years breaks down into a feasibility study period of about 2 years, a pivotal study period of about 5

[416] Kesselheim Day 4-PM 16:21-17:4; PX8000 Kesselheim ¶ 45.
[417] PX8004 Kesselheim Reply ¶ 22.
[418] *See* DX0289 Bailey Ex. 27.
[419] Zovighian Day 2-PM 72:13-18.
[420] Kesselheim Day 4-PM 90:11-15.
[421] Zovighian Day 2-PM 70:6-16, 71:9-12; PX1120-001.
[422] Zovighian Day 2-PM 70:20-71:8.
[423] *See* Kesselheim Day 4-PM 12:6-9, 21:7-13; PX8000 Kesselheim ¶ 60 & Table 2; *see also* Bailey Day 6-PM 29:8-14 (agreeing that it takes, on average, 8.5 years for a complex medical device to go from the start of an FDA EFS to FDA approval).

years, and a PMA application phase of about 1.5 years.[424]

164. J-Valve's and Trilogy's [redacted].[425] Defendants have not presented evidence to establish that any other TAVR-AR device would encounter appreciably shorter FDA regulatory timeframes. Instead, for example, Dr. Chetcuti testified as to a timeline consistent with that noted above, predicting Hanchor Valve would require seven and ten years to obtain U.S. commercial approval and an extra three to four years with a pre-existing commercial rival in the United States.[426] Dr. Kereiakes testified that, even when a device manufacturer is already enrolling patients in early clinical trials but has not yet begun a pivotal trial, they are "behind."[427]

165. A high-risk device in its early feasibility stage has only an approximately 29% chance of receiving FDA approval for commercial use.[428]

166. Evidence does not support Defendants' claim that other strategics, like Medtronic, are "fast followers" simply waiting for Edwards to establish the viability of the TAVR-AR market. Medtronic's Mr. Larkin disputed Defendants' definition of "fast follower" and explained that, with respect to TAVR-AS, Medtronic was not "waiting for Edwards to establish the viability of the space."[429] Instead Medtronic was "actively pursuing the space independently [and] happened to be second to market in the United States."[430]

167. [redacted]

[424] Kesselheim Day 4-PM 22:19-25; *see also* PX8000 Kesselheim ¶ 60 & Table 2.
[425] Kesselheim Day 4-PM 37:13-17, 40:11-15.
[426] Chetcuti Day 6-AM 42:2-3, 43:8-15; *see also* Wood Day 2-AM 51:25-52:3.
[427] Kereiakes Dep. 71:15-20.
[428] PX8000 Kesselheim ¶ 66; DX0289 Bailey Ex. 1.
[429] Larkin Day 2-AM 126:11-127:20.
[430] Larkin Day 2-AM 127:5-16.

[redacted]."[431] [redacted]

[redacted].[432]

168. In addition, data does not support Defendants' concept of a "fast follower." An analysis of TAVR-AR devices' regulatory timelines showed that the presence of a first-in-class TAVR-AS device did not result in consistently faster FDA approval of subsequent TAVR-AS devices.[433] Likewise, a similar analysis of the timing from acquisition to PMA approval of TAVR-AS devices showed no association between the timing of acquisition and the timeline of approval of these TAVR-AS devices.[434]

B. JenaValve Is Not a Flailing Firm

1. Legal Standard

169. Defendants failed to raise a failing firm, flailing firm, or weakened competitor defense in their Answers, and thus waived them. *See* JenaValve Answer; Edwards Answer; Fed. R. Civ. P. 8 (requiring parties to plead defenses).

170. Defendants' suggestion that "JenaValve will be left limping and financially insecure" if the Proposed Transaction is blocked,[435] however, is a veiled attempt to make a flailing firm or weakened competitor argument—a defense strongly disfavored by courts as "probably the weakest ground of all for justifying a merger." *FTC v. University Health*, 938 F.2d 1206, 1221 (11th Cir. 1991) (quotations omitted); *see also Aetna*, 240 F.Supp.3d at 92 (describing this defense as "the Hail-Mary pass of presumptively doomed mergers") (quoting *ProMedica Health Sys. v. FTC*, 749 F.3d 559, 572 (6th Cir. 2014)).

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[431] Castelli Dep. 128:22-23, 129:1-2.
[432] Castelli Dep. 141:9-11, 141:13-14.
[433] Kesselheim Day 4-PM 28:18-29:5; *see also* PX8000 Kesselheim ¶¶ 109-111.
[434] Kesselheim Day 4-PM 29:6-14.
[435] Edwards Answer 2.

171. Any such defense comes with stringent prerequisites that Defendants cannot meet. *See Aetna*, 240 F.Supp.3d at 92 (Defendants must "make a substantial showing that the acquired firm's weakness, which cannot be resolved by any competitive means, would cause that firm's market share to reduce to a level that would undermine the government's prima facie case.") (quoting *Univ. Health*, 938 F.2d at 1221). Courts reject a weakened competitor defense when "it is not certain" that the weakness of a weakened firm "cannot be resolved through new financing or acquisition by other than a leading competitor." *Univ. Health*, 938 F.2d at 1221 (quotations omitted).

172. Though Defendants suggest that JenaValve's options may be limited without the Proposed Transaction, Defendants certainly cannot show that JenaValve has no "options besides merging with [Edwards] that would have preserved competition." *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 988 F.3d 690, 715 (4th Cir. 2021).

173. Attempting to skirt the legal test for a failing firm, Defendants suggest that JenaValve is "struggling" and "limping."[436] Notwithstanding that there is no "limping firm defense," Defendants ignore that JenaValve's struggles are exacerbated or caused by Edwards. With the Proposed Transaction pending, JenaValve has limited options; it cannot operate independently, explore interest from other strategics, [redacted].[437] [redacted].[438]

174. Edwards [redacted]

[436] Day 1-AM 47:6-13 (EW Opening Arg.).
[437] Kilcoyne Day 1-PM 25:21-26:8, 127:24-128:12; PX1166-082-086.
[438] Kilcoyne Day 1-PM 53:3-23 (referencing PX2473-002), 103:9-104:8; Keltjens Day 5-AM 128:9-14.

[redacted].[439] JenaValve's VP of Finance testified that [redacted].[440] Dr. Pinto testified that JenaValve has not received any resources from Edwards to support the ARTIST trial[441] and wrote that he wished JenaValve was "independent so that we could make normal progress as we have and get our trial under way."[442]

2. JenaValve Will Have Interest From Alternative Acquirors, Has a Track Record of Successfully Raising Money, and Will Have Financing Options Post-Transaction

175. JenaValve recognizes it has meaningful alternatives to the Proposed Transaction, including a different buyer or attracting new investors as it has done successfully in the past.[443] For instance, other companies have repeatedly expressed interest in JenaValve over the years.[444] [redacted].[445] [redacted].[446] [redacted].[447] However, in lead up to the Proposed Transaction, JenaValve [redacted]

[439] Keltjens Day 5-PM 27:25-28:8.
[440] Sloan IH 100:6-9.
[441] Pinto Day 3-PM 117:18-119:13 (referencing PX2204-001).
[442] Pinto Day 3-PM 121:8-20 (referencing PX2227-002).
[443] PX2020-009.
[444] Kilcoyne Day 1-PM 21:6-16 (referencing PX2177-004).
[445] Larkin Day 2-AM 134:23-135:11, 138:19-139:21.
[446] Larkin Day 2-AM at 138:19-139:21.
[447] Larkin Day 2-AM 138:19-139:21,140:4-141:5; Larkin Day 2-PM 12:12-21.

[redacted] [448] In fact, [redacted].[449]

176. JenaValve remains an attractive acquisition target today because [redacted] [redacted].[450] Dan Dearen, a JenaValve board member, agrees; writing to JenaValve CEO John Kilcoyne on August 8, 2025, two days after the FTC filed its complaint in this matter, "you're about to get FDA approval and you have the best product in your space. . . . The Company's value is also about to go up dramatically after market launch."[451] And Mr. Dearen testified that "at some point down the road [JenaValve] will undoubtedly end up as part of a larger organization somewhere else."[452] Another JenaValve employee wrote after the FTC's complaint on August 6, 2025, "Can we get out and go for bigger bidders now? We are worth more today than we were a year ago. . . ."[453]

177. Today, [redacted].[454] [redacted] [redacted] [455]

178. Additionally, JenaValve will have financing options it currently cannot access. JenaValve's [redacted] [redacted].[456] JenaValve received inquiries from prospective investors while negotiating with

[448] Kilcoyne Day 1-PM 24:3-5; Keltjens Day 5-PM 10:22-11:22.
[449] Larkin Day 2-PM 16:8-15.
[450] Keltjens Day 5-PM 19:20-20:9.
[451] PX2282-001.
[452] Dearen Dep. 110:1-25.
[453] PX2465-002.
[454] Larkin Day 2-AM 142:5-8.
[455] Castelli Dep.186:25-187:14.
[456] Keltjens Day 5-PM 32:17-33:7.

Edwards but responded that it would not discuss financing due to the potential acquisition.[457] Other investors expressed interest even after the Proposed Transaction was announced.[458]

179. [redacted].[459]

180. JenaValve has received positive feedback from potential investors and has explored the possibility of Series C funding, which would carry JenaValve through a public offering.[460] JenaValve Chairman Jan Keltjens testified that the board and JenaValve's major investors have been planning to raise emergency financing from existing investors to fund the company while it considers options such as an alternative acquiror or pursuing an IPO.[461] [redacted],[462] [redacted].[463] [redacted].[464] Defendants' expert, Dennis McWilliams, testified that he thought it was likely JenaValve would successfully raise funding from its existing investors.[465]

3. JenaValve Has Ongoing Plans to Commercialize and Further Develop Trilogy

181. JenaValve has singlehandedly advanced Trilogy to the point it is today—the brink of FDA approval. As Mr. Kilcoyne boasted, Trilogy is the best TAVR-AR device out there now, JenaValve has recruited top doctors to use the Trilogy product, and Trilogy has already, and will

[457] Kilcoyne Day 1-PM 68:17-20; 69:13-70:9 (referencing PX2173).
[458] Kilcoyne Day 1-PM 70:25-71:9 (referencing PX2170).
[459] Kilcoyne Day 1-PM 92:10-14.
[460] Kilcoyne Day 1-PM 67:14-22, 67:23-68:14.
[461] Keltjens Day 5-PM 4:15-5:7, 15:14-20; DX0270-065 (July 2025 Board Deck).
[462] Kilcoyne Day 1-PM 105:9-22 (referencing PX2474).
[463] Kilcoyne Day 1-PM 105:25-106:17 (referencing PX2474).
[464] Kilcoyne Day 1-PM 106:18-107:10 (referencing PX2474).
[465] McWilliams Day 6-AM 84:17-86:11.

continue to, change lives.[466] JenaValve board member, Mr. Dearen, testified that "the future is bright" for JenaValve as a standalone company.[467]

182. JenaValve does not need Edwards to commercialize Trilogy. JenaValve is preparing to commercialize Trilogy in the United States [redacted], regardless of whether it is acquired by Edwards.[468] These preparations include site engagement, key launch targets, hiring more sewers to "blow the production plan out of the water," hiring and training new field staff, educating physicians, advocating for an AR-specific reimbursement rate, and securing Medicare coverage.[469] JenaValve has also been increasing its facilities' manufacturing capacity [redacted].[470]

183. [redacted].[471] [redacted].[472] [redacted].[473]

184. Not only is JenaValve gearing up for the launch of Trilogy, but it has plans to develop new indications and make improvements to Trilogy. JenaValve is working on multiple

[466] Kilcoyne Day 1-PM 62:13-17.
[467] Dearen Dep. 110:1-25.
[468] Baerenwald Dep. 49:20-50:5, 219:10-220:1; Darby Dep. 30:15-18, 31:4-8; 215:1-216:2; Spadaro Dep. 16:25-18:23, 69:2-6.
[469] Kilcoyne Day 1-PM 65:19-66:13 (referencing PX2303-009-027); PX2304; PX2306-002; PX2374; PX2361.
[470] Kilcoyne Day 1-PM 62:24-63:25; 86:11-22; 89:9-90:14; PX2034.
[471] Kilcoyne Day 1-PM 85:25-86:3.
[472] Kilcoyne Day 1-PM 91:2-8; PDX0004; PX0031-019; PX2461-005; PX2034-005, 006.
[473] *See infra* § XI.D.2.d.

projects, including larger valve sizes,[474] implementing its LVAD registry, and expanding its indication for intermediate and low-risk patients through its ARTIST trial.[475]

4. Defendants' Claims Regarding JenaValve's [redacted] Are Exaggerated

185. Despite Defendants' alarmist claims in their opening statements,[476] [redacted].[477] [redacted]"[478] [redacted].[479] [redacted][480]

186. Moreover, the FDA's deficiency letter does not suggest that Trilogy is unsafe and therefore unlikely to obtain FDA approval. [redacted].[481] [redacted].[482] [redacted].[483] Dr. Pinto testified that it would not be medically ethical to implant Trilogy if there were questions about its safety or durability.[484] Dr. Chetcuti "would not be

[474] Keltjens Day 5-AM 123:8-25.
[475] *See supra* § 2; Pinto Day 3-PM 104:4-25.
[476] Day 1-AM 48:6-16; 76:14-20 (EW Opening Arg.).
[477] Kesselheim Day 4-PM 38:6-8; *see supra* § V.
[478] Dearen Dep. 57:2-14, 62:2-19.
[479] Keltjens Day 5-PM 23:7-11; *see also* Kilcoyne Day 1-PM 99:24-101:3.
[480] Kilcoyne Day 1-PM 85:3-13; *see also* PX1390-001.
[481] Kilcoyne Day 1-PM 101:4-15.
[482] Kilcoyne Day 2-AM 14:1-14
[483] Kilcoyne Day 2-AM 14:1-14
[484] Pinto Day 4-AM 6:14-7:8.

implanting [Trilogy] in patients" if he had any concerns about its safety.[485]

187. [redacted].[486] [redacted].[487]

188. [redacted].[488] [redacted].[489] [redacted].[490]

189. On the other hand, Edwards witnesses who opined on JenaValve's deficiency letter had very limited (or current) information on the matter: [redacted];[491] Mr. Zovighian admitted to have not even knowing "what's in the letter";[492] and, [redacted].[493]

[485] Chetcuti Day 6-AM 36:2-11.
[486] Kilcoyne Day 2-AM 11:8-11, 12:5-13:5; PX2380-001.
[487] Kilcoyne Day 2-AM 11:23-12:4.
[488] Kilcoyne Day 2-AM 7:13-9:13; PX2547-001-02; PX1166-018-19.
[489] PX2547-002.
[490] Kilcoyne Day 2-AM 10:17-19.
[491] Wood Day 2-AM 116:1-117:10.
[492] Zovighian Day 2-PM 92:9-16.
[493] Sirimanne Day 5-PM 99:10-100:3.

C. JC Medical Was Not a Failing Firm and Genesis' Decision to Divest Its U.S. Operations Is Irrelevant to the Antitrust Concerns Before the Court

190. As explained in XI.B.1, Defendants waived a failing firm, flailing firm, or weakened competitor defense, which is the weakest ground for justifying a merger and has stringent prerequisites that Defendants cannot meet. Nevertheless, Defendants' claims that JC Medical would have "shut down" absent Edwards' acquisition is clearly an attempt to make a *second* failing firm defense. There is no legal basis for permitting an anticompetitive acquisition because the overlap stems from an *earlier* acquisition of a purportedly distressed firm. Nonetheless, when Edwards agreed to acquire JenaValve, JC Medical's U.S. business was not distressed as it was already owned by Edwards.

191. In any case, Defendants have not shown that JC Medical had no options besides merging with Edwards that would have preserved competition. Genesis MedTech, a well-capitalized firm, was the prior owner of JC Medical and JC Medical's U.S.-based team [redacted].[494] Defendants do not suggest that Genesis MedTech was failing. Rather, Genesis MedTech made the business decision to either spin off JC Medical's U.S. operations or seek outside funding for its U.S. pivotal trial.[495] Given the ultimate terms of the sale—$115 million upfront, $200 million in potential milestone payments, and a $25 million investment in Genesis Medtech—it is highly unlikely Genesis Medtech would have abandoned the valuable J-Valve assets in the absence of the Edwards acquisition.[496] Indeed, JC Medical's CEO conceded that he did not know Genesis MedTech's plans for the U.S. J-Valve assets if the Edwards acquisition did not go through.[497]

[494] Turco Day 4-AM 79:2-5, 103:14-24; Concepcion Day 3-PM 15:12-24.
[495] Turco Day 4-AM 80:13-24.
[496] Turco Day 4-AM 94:13-18; Turco Day 4-PM 5:1-15; PX1040-001.
[497] Turco Day 4-PM 7:7-9.

192. Defendants' claims about the lack of alternative acquirers or investors in JC Medical are inconsistent with the record. Genesis MedTech did not hire an investment banker to lead a formal sale process.[498] Mr. Bobo testified that Dr. Turco told him by early February 2024 that JC Medical was in danger of being shut down and no one else was interested,[499] but Dr. Turco testified that Edwards was the first potential buyer he contacted, and he continued to have conversations with other potential buyers into April 2024, [redacted].[500] [redacted]"[501] [redacted].[502]

193. In April 2024, Edwards was the first company to provide a term sheet to JC Medical and it included an exclusivity clause.[503] JC Medical then "let the other companies know that we had an existing term sheet so that we could, then, turn the conversations off with those other companies, given the existing exclusivity."[504] Dr. Turco testified, "once we had begun to work with Edwards, then, in the term sheet, it was important for us to let Johnson & Johnson, Boston Scientific, and Abbott, as well as Medtronic, know that we were . . . in formal negotiations with Edwards."[505] Those potential buyers did not pass until Edwards' term sheet prompted Dr. Turco to press them to match Edwards' timeline, which they were unable to do.[506]

194. JC Medical had additional options beyond an acquisition. The venture capital fund

[498] Turco Day 4-AM 81:6-7.
[499] Bobo Day 3-AM 26:17-27:24.
[500] Turco Day 4-AM 81:21-25, 82:21-83:9, 84:11-14.
[501] Larkin Day 2-AM 145:21-146:1.
[502] Larkin Day 2-AM 142:9-144:3, 144:8-12.
[503] Turco Day 4-AM 84:15-23.
[504] Turco Day 4-AM 84:24-85:5.
[505] Turco Day 4-AM 85:6-11.
[506] Turco Day 4-AM 85:15-87:5; DX0104-001-02; Larkin Day 2-AM 143:16-144:3.

Vensana expressed interest in investing in JC Medical before JC Medical entered exclusivity with Edwards.[507] Vensana reengaged when it believed Edwards had selected JenaValve over JC Medical, putting JC Medical back on the market.[508] JC Medical informed Vensana that it was too late because "Edwards acquired both J-Valve and Jena. Both platforms."[509]

D. Defendants Fail to Substantiate Cognizable Efficiencies Sufficient to Prevent Harm From the Proposed Transaction

1. Legal Standard

195. Efficiencies cannot excuse creation of a monopoly. *See Alliant*, 808 F.Supp. at 21.

196. The Supreme Court and the D.C. Circuit have questioned whether efficiencies can ever provide a legal defense for an anticompetitive transaction. *Anthem*, 855 F.3d at 353-56 (citing *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 580 (1967)) ("Possible economies cannot be used as a defense to illegality. Congress was aware that some mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition."); *Staples*, 970 F.Supp. at 1088-89 (discussing uncertainty over the efficiencies defense).

197. The Supreme Court explained in *PNB* that "a merger the effect of which 'may be substantially to lessen competition' is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." 374 U.S. at 371; *see also Anthem*, 855 F.3d at 355 ("[O]nce it is determined that a merger *would* substantially lessen competition, expected economies, however great, will not insulate the merger from a [S]ection 7 challenge.") (quotations omitted); *Heinz*, 246 F.3d at 720-21.

[507] Turco Day 4-AM 84:1-10.
[508] PX1160-002; Turco Day 4-AM 88:25-90:12.
[509] PX1160-002; Turco Day 4-AM 90:9-12.

2. Defendants' Mislabeling of Claimed Efficiencies as Equities Has Been Rejected by Courts

198. The "efficiencies defense" argues "the merger will generate significant efficiencies and thus enhance the merged firm's ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products." *Tapestry*, 755 F.Supp.3d at 480 (quoting *ProMedica*, 749 F.3d at 571). Perhaps to evade courts' scrutiny of efficiencies claims, merging parties try to disguise efficiencies defenses by labeling them "procompetitive benefits." *See, e.g.*, *FTC v. Hackensack Meridian Health, Inc.*, 30 F.4th 160, 175-76 (3d Cir. 2022); *Tapestry*, 755 F.Supp.3d at 481.[510] Nonetheless, the D.C. Circuit and others have consistently applied the efficiencies legal framework to assess contended "procompetitive benefits" in hospital, consumer product, health insurance, and life sciences R&D mergers, among others. *See, e.g.*, *Anthem*, 855 F.3d at 354-67; *Hackensack*, 30 F.4th at 175-76; *Heinz*, 246 F.3d at 720-22; *Illumina*, 88 F.4th at 1059-61. This case is no different—whether analyzed as efficiencies, equities, or "procompetitive benefits," Defendants' evidence falls short.

199. For example, in *Hackensack*, defendants—two merging hospitals—claimed that the court "need not apply" the efficiencies defense's "stringent standard" when evaluating "a panoply of procompetitive benefits" that could result from the transaction but should weigh the presumed benefits against any likely anticompetitive effects proven by the plaintiff. 30 F.4th at 175-76. The alleged benefits included increasing hospital capacity, expanding types of care, and

[510] Defendants have cited *FTC v. Community Health Systems, Inc.*, 736 F.Supp.3d 335, 374 (W.D.N.C. 2024), *vacated by FTC v. Novant Health, Inc.*, No. 24-1526, 2024 WL 3561941 (4th Cir. July 24, 2024), as an example of a district court relying on procompetitive benefits, but that decision was stayed by the Fourth Circuit on the FTC's motion arguing that the district court improperly applied the efficiencies and flailing firm legal standards. *See* FTC Motion For An Injunction Pending Appeal, Dkt. No. 5, *FTC v. Novant Health, Inc.*, No. 24-1526 (4th Cir. June 11, 2024). The decision was vacated after the defendants abandoned the transaction. Order Granting Motion to Vacate Decision & Dismiss Appeal, Dkt. No. 26, *id*. The district court's opinion therefore is no longer good authority, and it is improper to cite to it.

quality improvements. *Id.* The Third Circuit rejected this argument, concluding that defendants' "procompetitive benefits argument [was] an efficiencies defense." *Id.* at 176. Similarly, in *Tapestry*, defendants asserted the acquiring firm would "revitalize" the acquired firm, expanding its output through superior technology, "supply chain," and "talent." 755 F.Supp.3d at 479-81. Defendants "dispute[d] that 'this evidence must meet the formal elements of an efficiencies defense to be considered . . . .'" *Id.* at 481. But the district court disagreed and evaluated these claims "in the framework of an efficiencies defense." *Id*.

200. Here, Defendants assert that the Transaction will improve product quality and will lead to increased output just as the defendants did in *Hackensack* and *Tapestry*. Like in *Hackensack* and *Tapestry*, this Court should assess the purported benefits under the "rigorous" efficiencies standard. *See H&R Block*, 833 F.Supp.2d at 89 (quoting *Heinz*, 246 F.3d at 721).

201. Numerous courts have evaluated purported benefits like those claimed by Defendants as efficiencies. *See, e.g.*, *FTC v. Kroger Co.*, 2024 WL 5053016, at *22-*24 (D. Or. Dec. 10, 2024). For example, in *Illumina*, the Fifth Circuit treated the acquiring firm's alleged ability to "'accelerate' FDA approval and payer coverage," and thus increase output for the acquired firm's product and R&D improvements, as efficiencies. 88 F.4th at 1060-61. The D.C. Circuit, in both *Heinz* and *Anthem*, assessed claimed product quality improvements as efficiencies. *Heinz*, 246 F.3d at 721-22; *Anthem*, 855 F.3d at 360. The Eighth and Ninth Circuits have done the same. *FTC v. Sanford Health*, 926 F.3d 959, 965-66 (8th Cir. 2019); *Saint Alphonsus Med. Ctr.-Nampa, Inc. v. Saint Luke's Health Sys., Ltd.*, 778 F.3d 775, 791-92 (9th Cir. 2015).

202. Defendants' semantics are irrelevant. Efficiencies by any name must be subject to "close judicial scrutiny." *Wilhelmsen*, 341 F.Supp.3d at 72.

3. Defendants Do Not Meet the Established Efficiencies Standard

203. Holding Defendants to the proper legal standard is vitally important here, where Edwards would be the sole remaining TAVR-AR device company for the foreseeable future. The D.C. Circuit held that cases with "high market concentration levels . . . require, in rebuttal, proof of extraordinary efficiencies." *Heinz*, 246 F.3d at 720. Defendants' claimed procompetitive benefits thus should be reviewed under the strict and well-established efficiencies rubric.

204. Courts apply a "stringent standard" when assessing efficiencies claims. *Hackensack*, 30 F.4th at 176; *see also Wilhelmsen*, 341 F.Supp.3d at 72 ("[T]he court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior.") (quoting *Heinz*, 246 F.3d at 721); *Penn State Hershey*, 838 F.3d at 349 (describing the efficiencies standard as "rigorous").

205. Defendants must establish that claimed efficiencies are cognizable, meaning verifiable, merger specific, and likely to be passed through to consumers. *Sysco*, 113 F.Supp.3d at 82; *Illumina*, 88 F.4th at 1059-61 ("an efficiency defense is very difficult to establish"); *Aetna*, 240 F.Supp.3d at 94 (efficiencies must benefit consumers in the relevant markets and "courts will give weight only to efficiencies that are cognizable—i.e., merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service.") (citation omitted). Defendants, however, do not attempt to verify or calculate any claimed benefit from the Proposed Transaction. *See Illumina*, 88 F.4th at 1060-61. Nor do Defendants show that their proposed efficiencies could only be achieved by Edwards and not by another buyer or a better-funded, independent JenaValve. *See, e.g.*, *Cardinal Health*, 12 F.Supp.2d at 62 ("[E]fficiencies, no matter how great, should not be considered if they could also be accomplished without a merger.").

206. Defendants must "substantiate efficiency claims so that it is possible to verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific." *H&R Block*, 833 F.Supp.2d at 89 (cleaned up). Defendants cannot rely on the "estimation and judgment of" their executives. *See id.* at 91. Instead, they must supply "independent verification" of purported efficiencies. *See Wilhelmsen*, 341 F.Supp.3d at 73. Defendants do no such thing.

207. Neither of Defendants' experts used the words "verify," "verifiable," or "verified" in their reports. Neither of Defendants' experts modeled or quantified the "likelihood and magnitude of each asserted efficiency" or estimated "when each [efficiency] would be achieved (and any costs of doing so)," as required to substantiate efficiencies. *H&R Block*, 833 F.Supp.3d at 89; *see IQVIA*, 710 F.Supp.3d at 399.

208. Despite Defendants' assertions that the Transaction will save lives, Defendants' own economic expert does not attempt to calculate, verify, or perform a "lives saved" analysis.[511] In *Illumina*, the Fifth Circuit rejected as unverifiable Illumina's unquantified contention that the merger would create significant R&D efficiencies. 88 F.4th at 1060; *see id.* at 1061 (rejecting FDA approval acceleration claims, in part, because "Illumina's own financial modeling of the merger did not assume that Galleri's widespread commercialization would be accelerated").

209. The D.C. Circuit has referred to innovation efficiency claims similar to Defendants' as "often a speculative proposition." *Heinz*, 246 F.3d at 722-23 (citing 4A Philip E. Areeda et al., *Antitrust Law* ¶ 975g (4th ed. 2016) (describing the "truly formidable" "proof problems" in establishing innovation efficiencies)). In *FTC v. CCC Holdings*, the court rejected an argument

[511] Bailey Day 6-PM 71:25-72:1.

that "the merged entity will spend considerably more on new product research and development than the two companies spend individually," because the acquirer "could already afford to increase R & D funding on its own if its shareholders were willing to trade off their return. . . . There is no reason to believe that the merger will eliminate this pervasive problem." 605 F.Supp.2d 26, 75 (D.D.C. 2009) (cleaned up).

210. The Supreme Court has recognized the "extremely limited" probative value of evidence created while a lawsuit is "threatened or pending," *United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 504-05 (1974), which can be "dripping with motivations to misrepresent," *Certain Underwriters at Lloyd's, London v. Sinkovich*, 232 F.3d 200, 204 n.2 (4th Cir. 2000) (quoting *Hoffman v. Palmer*, 129 F.2d 976, 991 (2d Cir. 1942)). *See also Aetna*, 240 F.Supp.3d at 80-81; *Hackensack*, 2021 WL 4145062, at *27.

211. Promises about post-merger conduct are thus entitled to little weight. *See Bertelsmann*, 646 F.Supp.3d at 50 (CEO's promise about post-merger conduct "lack[ed] credibility" because it "would not be profit-maximizing and is thus unreliable evidence of future conduct" and could "be broken at will"); *Kroger*, 2024 WL 5053016, at *24 ("Despite defendants' best intentions to follow through on their promises at this moment, the business realities on the ground after the merger may change what defendants are able to invest or what is in their best interest to invest."); *Staples*, 970 F.Supp. at 1089 (finding Defendants' claimed efficiencies unreliable because they exceeded projections presented to the board of directors when approving the transaction).

212. As detailed in Section III, the "record contain[s] compelling evidence of the deterioration of the merging parties' relationship," which this Court and other courts in this district have found is instructive for assessing cognizability. *See Anthem*, 236 F.Supp.3d at 245-

46 (detailing disagreements between the merging parties, including letters accusing the other of breaching the merger agreement); Mem. Op. Granting Pl.'s Mot. to Compel Disc. Resps. from Def. JenaValve Technology, Inc. 6, Dkt. No. 78 (citing *United States v. Anthem, Inc.*, No. 16-cv-1493 (ABJ), 2016 WL 8461264, at *5 (D.D.C. Oct. 6, 2016), *report and recommendation adopted*, 2016 WL 11164028 (D.D.C. Oct. 14, 2016) (finding that documents revealing a state of hostility between merging parties were "directly relevant" to assessing whether the parties' proposed efficiencies from the merger were likely to transpire)).

4. Defendants Did Not Quantify Any Merger-Specific Efficiencies

213. Defendants did not attempt to quantify or calculate the benefit of any alleged merger-specific efficiencies or synergies.[512] First, Defendants did not devote resources to plan for integration or to calculate synergies from the Proposed Transaction[513] and lack a "detailed plan" on how to integrate JenaValve into Edwards.[514] JenaValve's CEO corroborated this, stating that there is no integration planning taking place.[515] Second, Edwards' financial model does not contemplate synergies from the JenaValve transaction, and its finance group noted that any synergies could well be offset by integration costs.[516] In fact, Edwards' integration lead referred to integrating JenaValve as "the shitstorm we are headed for."[517] Finally, Dr. Bailey also confirmed she did not perform any quantitative analysis of merger-specific efficiencies or synergies.[518]

[512] Zovighian Day 2-PM 67:7-9.
[513] Zovighian Day 2-PM 67:10-12.
[514] Zovighian Day 2-PM 66:21-67:4; Wood Day 2-AM 53:11-24.
[515] Kilcoyne Day 1-PM 54:4-14.
[516] PX1587-005; Bobo Day 2-PM 119:10-120:5, 121:1-5 (referencing PX1587-003, -005).
[517] PX1335-003.
[518] Bailey Day 6-PM 71:15-17.

214. Defendants' "lives saved" claims are not verifiable. Dr. Bailey admitted that she did not perform any analysis to quantify the potential lives saved as a result of the Proposed Transaction.[519] Defendants point to an accelerated sales forecast to claim that the Proposed Transaction will save lives but testimony confirms that this forecast was not intended to analyze potential lives saved.[520] Moreover, that forecast was created by JenaValve, based on assumptions it made about Edwards with no information provided by Edwards.[521] Further, the forecast was not unique to Edwards and was provided to other large strategics, [redacted].[522] Most importantly, Edwards has not adopted this forecast as its own.[523]

5. Accelerated Commercialization is Contrary to the Evidence and Not Merger Specific

215. Defendants failed to substantiate accelerated commercialization claims or how their claimed efficiencies would benefit consumers and outweigh the competitive harm from the Proposed Transaction.[524] In December 2023, Mr. Kilcoyne presented Edwards' leadership team [redacted]"—that is, what Mr. Kilcoyne [redacted]"[525] [redacted].[526] [redacted]

[519] Bailey Day 6-PM 71:25-72:2.
[520] Kilcoyne Day 1-PM 75:25-76:4 (referencing PX0031-019).
[521] Kilcoyne Day 1-PM 76:5-77:13 (referencing PX0031-019).
[522] Kilcoyne Day 1-PM 77:22-24, 79:2-7 (referencing PX2144-006).
[523] Bobo Day 2-PM 126:13-127:4, 148:1-149:9 (referencing PDX0006).
[524] PX8001 Wilson ¶¶ 124-126.
[525] Bobo Day 2-PM 143:19-144:4, 145:4-8 (referencing PX0031-018-019); PX1199.
[526] Darmali Dep. 12:19-13:5, 101:23-103:7, 107:5-109:8; PX1159 [redacted]

[redacted].[527] Additionally, Edwards has not taken steps or developed a plan that identifies the number of commercial employees necessary to launch Trilogy in the U.S.[528] Edwards's CFO testified that Edwards has no final plans on how much funding to allocate to JenaValve's R&D efforts, operations, or SG&A, or to the commercial sale of Trilogy.[529]

216. Edwards plans to rely on JenaValve's existing facilities to manufacture Trilogy valves and delivery systems, for at least three years, calls into question any claims of acceleration.[530] Indeed, whether standalone or acquired by a strategic, Trilogy must be manufactured in these facilities for the near-to-midterm because the FDA has approved them and the process of approving new sites is likely to take years.[531] Nor has Edwards approved additional investment for JenaValve manufacturing projects, including manufacturing lines.[532]

217. Other strategic buyers could accelerate sales of Trilogy to the same extent as Edwards.[533] Mr. Bobo testified that any medical device company with deep expertise in heart valves could bring similar resources to bear on Trilogy manufacturing and supply chain.[534]

218. Defendants' industry expert, Mr. McWilliams, relied on Edwards' commercialization of TAVR-AS to develop post-acquisition projections while ignoring the companies' own

[527] PX1016-001; Bierman Day 3-AM 82:2-19 (referencing PX1390); PX1390-001 [redacted]; Bobo Day 2-PM 126:13-127:4, 148:1-149:9; PX0031-018-019; PX1159 [redacted]).
[528] Bierman Day 3-AM 87:12-18.
[529] Ullem Dep. 120:23-121:2, 122:14-123:2, 123:25-124:12.
[530] PX1303-009; Bobo Day 2-PM 122:6-123:3 (referencing PX1303-009); Kilcoyne Day 1-PM 64:9-18.
[531] Bobo Day 3-AM 25:4-26:9.
[532] Kilcoyne Day 1-PM 64:1-8.
[533] Kilcoyne Day 1-PM 79:8-25.
[534] Bobo Day 2-PM 127:5-15.

ordinary-course projections.[535] Mr. McWilliams conceded that [redacted] [redacted].[536]

219. Although TAVR-AR doctors may opine on AR treatment options, they lack personal knowledge to opine on Edwards' TAVR-AR commercialization and manufacturing plans.[537] Dr. Chetcuti testified that he does not have personal knowledge of Edwards' plans if the Proposed Transaction closes,[538] and Dr. Vahl likewise lacks personal knowledge about Edwards' plans for Trilogy and thus has no basis to opine on any purported efficiencies that may or may not arise.[539]

220. In addition, JenaValve's low commercial sales in Europe do not call into doubt whether it can successfully commercialize Trilogy.[540] [redacted].[541] JenaValve employees have noted that if valves were only sold in the United States, JenaValve could cover its monthly expenses.[542]

6. Edwards' Claimed Innovation Efficiencies Cannot Be Verified and Are Not Merger Specific

221. Defendants' claim that the Proposed Transaction will lead to greater innovation is speculative. To take over and effectively innovate on Trilogy, Edwards must, and intends to,

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[535] McWilliams Day 6-AM 96:3-22.
[536] McWilliams Day 6-AM 130:9-24.
[537] *See, e.g.*, Thourani Dep. 149:1-150:8, 152:9-153:7.
[538] Chetcuti Day 6-AM 28:25-29:16.
[539] Vahl Day 4-AM 50:21-51:24.
[540] PX8005 Wilson Reply ¶ 73.
[541] Keltjens Day 4-AM 121:22-122:11, 126:5-21; PX2461-001, 003; PX8005 Wilson Reply ¶ 73; *see also* PX2291-005.
[542] PX2307-001. Dr. Vahl's testimony regarding JenaValve's European operations is based entirely on hearsay; he is not employed by any clinical sites in Europe and lacks first-hand experience. Vahl Day 4-AM 54:6-19.

retain key JenaValve personnel, such as the R&D team who possess "material technical and black art awareness of valve" that is a "body of information that is super important to be able to manufacture to the quality and the performance required," and "the field and marketing team [who] have deep expertise in aortic regurgitation that would be valuable to commercialization."[543] But these employees may not join Edwards—some told Mr. Kilcoyne that "[b]ased upon what I read in the FTC report – I don't trust EW and don't think I would want to work there anyway."[544] Other medical device companies with expertise in heart valves could bring the same or similar resources to bear on Trilogy manufacturing and supply chain and could make the same or similar improvements or innovations.[545] Edwards SVP of Engineering doubted that it "could 'easily' incorporate [redacted] into Trilogy because [redacted]"[546]

222. Defendants' Gen 2 Trilogy device innovation assertions are also speculative and unsupported. There are currently no efforts or "detailed plan[s]" to integrate JenaValve into Edwards including as it relates to future innovation.[547] For example, one Edwards executive testified "it's a little premature to be thinking about next generation" Trilogy device.[548] In fact, [redacted][549] and other evidence suggests Trilogy will be Edwards' "Gen 1" device and J-Valve will be its "Gen 2" device.[550] Dr. Pinto also testified that no one at Edwards has made any promises to continue to

[543] Bobo Day 2-PM 125:7-126:12 (referencing PX1575-010-011); Bobo Day 3-AM 51:19-52:2, 52:7-53:2 (referencing DX0235-010-011).
[544] PX2282-002.
[545] *See* Bobo Day 2-PM 127:5-15.
[546] PX1232-001.
[547] Zovighian Day 2-PM 66:21-67:4; Wood Day 2-AM 52:10-53:10.
[548] Lippis Dep. 26:8-27:11.
[549] PX1253-006, 063-69.
[550] PX1394-003.

develop a next generation Trilogy or continue the JenaValve large valve program.[551] Edwards VP of Strategy confirmed Edwards has not determined whether it will even continue JenaValve's large valve program,[552] the innovative pursuit designed by JenaValve given "competitor J-Valve already ha[d] a large valve size in portfolio."[553] Finally, Dr. Bailey did not perform any analysis to determine if it would be profitable for Edwards to develop two second-generation TAVR-AR devices instead of one.[554]

223. Nor has Edwards developed a plan for a future hybrid TAVR-AR device that uses technology from JenaValve and JC Medical.[555] First, Dr. Bailey did not quantify any alleged acceleration of the development of Trilogy as a result of the Proposed Transaction.[556] Second, Edwards lacks the necessary JenaValve information and data to define the scope of a hybrid Gen 2 TAVR-AR design; any claim to the contrary is unsupported.[557] Such a device would also need to undergo pre-clinical testing and clinical trials, which Edwards has not begun to plan.[558] Although some internal documents reference an "AR Next Gen 2.0" system, these documents are limited and lack specificity.[559] Here, Edwards' next Gen 2.0 AR device does not commit to combining JenaValve and JC Medical technology; rather, Edwards suggests only that such a device may include technology from "JenaValve Trilogy Gen 1.0 *and/or* JC Medical J-Valve Gen 1.5 into an Edwards Gen 2.0 AR system."[560] However, the same AR Next Gen 2.0 valve,

[551] Pinto Day 4-AM 9:20-23.
[552] Bierman Day 3-AM 87:23-88:1.
[553] PX2186-024-025; *see also* PX2183-007 ("JVT urgently needs a larger valve to adequately treat the full range of AR patients and maintain a competitive advantage over J-Valve.").
[554] Bailey Day 6-PM 72:3-6.
[555] PX1013-002; *see* PX1239-004.
[556] Bailey Day 6-PM 71:18-20.
[557] Wood Day 2-AM 52:21-53:10; PX1253-062-067, 082.
[558] *See* PX1013-002 ("[T]his is the product that we would need a clinical trial . . .").
[559] PX1253-081-82.
[560] PX1253-082 (emphasis added).

[redacted].[561]

7. Edwards Faces Its Own Resource Constraints and Uncertainty as a Standalone Company

224. Edwards' resource constraints and goal to achieve double-digit revenue growth and meet publicly disclosed earnings per share targets,[562] along with its history of reprioritizing and deprioritizing programs, undermine its promises to fund Trilogy R&D.[563] First, in July 2024, Edwards entered into four acquisition agreements (including the Proposed Transaction), all of which require continued R&D investments and are "[m]assive undertaking[s]," that "require significant reorg[anization]" of resources.[564] Second, Edwards plans to reduce its R&D spending as a percentage of its revenue over the next several years, and Mr. Zovighian testified that Edwards "cannot go higher" with its R&D spend "or I'm going to be killed by investors."[565] Third, Edwards has periodically "reprioritize[d]" its spending on projects to align investment with its strategic priorities, and for projects that are de-prioritized, Edwards may spend less, delay spending, or cancel the project altogether.[566] Per Mr. Zovighian, "a commitment to fund

[561] PX1253-083.
[562] PX1137-031 (Zovighian comments: "double digit top line is king; [i]f not, EPS becomes critical"); PX1561-002 (Bobo concerned that finance may look at budgets for recent acquisitions and "conclude[] that we are significantly off the EPS mark."); Bobo Day 2-PM 138:3-10, 139:3-140:2, 141:13-142:6; Zovighian Day 2-PM 66:9-12; *see also* PX1209-001 (noting that Edwards has "received a lot of negative feedback from Wall Street analysts after the earnings call.").
[563] Bobo Day 2-PM 141:2-12; Zovighian Day 2-PM 52:4-18.
[564] Zovighian Day 2-PM 108:10-109:5 (referencing PX6002-041); PX1460-001; PX1209-001.
[565] Bobo Day 3-AM 10:19-11:25; Zovighian Day 2-PM 51:15-52:3, 66:16-18. Although Edwards increased its overall R&D expenses as of Q3 2025, this was largely driven by higher performance-based compensation expenses and partially offset by decreased investments in TAVR. *See* Zovighian Day 2-PM 107:11-108:3 (referencing PX6037-043).
[566] Bobo Day 2-PM 141:2-12; Zovighian Day 2-PM 52:4-18; Wood Day 2-AM 27:7-28:6; PX1270-002; PX1003-013 (indicating "[l]imited flexibility within operating budget to fund additional growth initiatives"); PX1450-029.

R&D today," even if sincere, "is not a commitment to fund that R&D project forever."[567] For example, after developing CENTERA, a self-expanding TAVR-AS device, Edwards cancelled the project because Edwards' balloon-expandable TAVR-AS device (SAPIEN) had better clinical data.[568] As a result, while Edwards executives claim TAVR-AR is a high priority, its 2025 TAVR-AR operating expense [redacted],[569] and Edwards has no final plans allocating funding to JenaValve.[570]

225. [redacted].[571] [redacted].[572] As Dr. Hack of Bain Capital testified: "the simple fact of an acquisition, I think by definition, puts into question any actions that company was taking before the acquisition. Because now that it's been acquired by somebody else, it's at the strategic direction of somebody else."[573] Edwards' CEO testified that [redacted].[574]

8. Edwards Intends to Reduce Investment in JenaValve if the Proposed Transaction Closes

226. In February 2025, Edwards' finance team, including the CFO, reached out to the CEO to seek his input on how to deliver on guidance announced to investors on Earnings Per

[567] Zovighian Day 2-PM 54:24-55:2.
[568] Bobo Day 3-AM 10:1-18.
[569] Bobo Day 3-AM 12:18-13:6, 70:14-15; PX1424-007.
[570] Ullem Dep. 122:14-123:2, 123:25-124:12.
[571] Zovighian Day 2-PM 75:20-76:4, 76:17-20, 76:24-2; Castelli Dep. 193:22-194:8.
[572] Zovighian Day 2-PM 76:5-7, 77:3-5.
[573] Hack Dep. 147:17-148:13.
[574] Zovighian Day 2-PM 77:12-18.

Share (EPS), a measure of financial performance.[575] In response to the CEO's suggestion to reduce "JenaValve burn," the finance team proposed [redacted].[576]

227. In March 2025, Edwards modeled [redacted] compared to JenaValve's own plan.[577] At that time, Edwards had not conducted any additional diligence or received further information from JenaValve since the acquisition agreement.[578] The [redacted] was reported to Edwards' executive team as part of the company's Management Business Review process.[579] [redacted].[580]

9. Potential Synergies From Alternative Acquirors Show Defendants' Claims Lack Merger Specificity

228. While the Defendants claim no alternative acquiror exists, the record suggests not only that there are potential alternative acquirors[581] but that such acquirors may be better suited to achieve synergies with JenaValve. First, Mr. Larkin testified that Medtronic has expertise in developing and commercializing medical devices for the U.S. and [redacted] required for TAVR approval.[582] Steve Sloan also opined that Medtronic would be able to help JenaValve scale manufacturing capability.[583] [redacted]

[575] Zovighian Day 2-PM 56:1-4, 56:24-57:20, 58:21-59:7; PX1118-002.
[576] Zovighian Day 2-PM 55:3-6, 55:17-25, 60:8-24; PX1118-001.
[577] Zovighian Day 2-PM 60:2-7, 62:16-19, 62:23-63:1-12; *compare* PX1118-002-03 *with* PX1134-004.
[578] Zovighian Day 2-PM 63:9-20.
[579] Zovighian Day 2-PM 64:2-21, 112:9-17; PX1134-001.
[580] Zovighian Day 2-PM 102:13-23, 110:24-111:2, 112:18-20.
[581] Sloan IH 63:4-15; Castelli Dep. 186:25-187:14.
[582] Larkin Day 2-AM 123:12-20.
[583] Sloan IH 214:5-20.

[redacted].[584] Indeed, because other heart valve companies have experience with porcine tissue and self-expanding valves like Trilogy, experience that Edwards lacks, these companies might more rapidly innovate or improve Trilogy. Likewise, these other heart valve companies could equally bring purported improvements to JenaValve's quality programs and clinical trials.[585] Third, Edwards' TAVR-AS experience is not unique, as both Medtronic and Abbott have successful TAVR-AS devices.[586] Finally, Defendants' expert Dr. Bailey testified that she did not analyze any potential impact to consumers if JenaValve is acquired by a different medical device company.[587]

10. Edwards' Track Record with J-Valve Does Not Demonstrate That It Would Enhance JenaValve

229. Edwards has not done detailed integration planning, in part because they need all hands on deck to try to fix J-Valve and cannot dedicate any engineering resources for JenaValve's integration.[588] Edwards' executives claim that ownership of J-Valve demonstrated it would improve JenaValve, but the record shows no improvement relative to JC Medical's pre-acquisition plans. First, J-Valve's progress has slowed since Edwards acquired it. [redacted][589] [redacted].[590] [redacted]

[584] Kilcoyne Day 1-PM 97:12-98:11 (referencing PX2146-011); *see* PX3003-051 [redacted]; PX3004-004 [redacted]
[585] Bobo Day 2-PM 127:24-128:6; Larkin Day 2-AM 123:12-20.
[586] Wood Day 2-AM 17:10-20; Bierman Day 3-AM 116:3-13.
[587] Bailey Day 6-PM 72:16-20.
[588] Bobo Day 3-AM 42:6-45:22.
[589] PX1048-007; Sirimanne Day 5-PM 94:24-95:5.
[590] Concepcion Day 3-PM 19:1-16.

[redacted].[591]

XII. Witness Credibility

A. Investigation and Litigation Impact on Defendants' Documents

230. Evidence shows that the FTC's investigation and litigation may have impacted the nature of documents created by Defendants. For example, on May 22, 2024, Mr. Wood and Mr. Bobo exchanged texts regarding potential contractual terms for the JenaValve agreement to address the possibility that the merger might be blocked due to antitrust concerns.[592] [redacted]

[redacted].[593]

231. Other evidence shows that employees in both companies were warned of the risk of antitrust review in creating documents. In January 2025, Edwards' Head of Global Supply Chain Integration emailed other Edwards employees "FYI, moving forward, let's don't write anything about JV down, as it can get subpoenaed 😊 nothing juicy in your notes, just a good practice[.]"[594] In May 2025, an Edwards executive emailed CFO Mr. Ullem that, in formulating Edwards' 2026 annual operating plan, "AR was handled carefully this submission due to the FTC review."[595] Likewise, JenaValve's Vice President of R&D warned another employee sharing news of the FTC's litigation: "Not appropriate to discuss here or in any medium. Please remind others not to post anything about this on Zoom, text, email, notebooks . . . etc. thanks."[596]

B. Defendants' Doctors and Their Lawyer

232. None of the doctors called by Defendants—Dr. Chetcuti, Dr. Thourani, or Dr.

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[591] Concepcion Day 3-PM 21:12-22; Wood Day 2-AM 51:25-52:9.
[592] PX1085; Bobo Day 2-PM 117:11-118:17.
[593] DX0114.
[594] PX1300-001.
[595] PX1537-001.
[596] PX2465-002.

Vahl—have any knowledge of Edwards' or JenaValve's plans with or without the Proposed Transaction, or have had any discussions with either company about the Proposed Transaction.[597] Instead, Edwards' attorneys shared with Dr. Chetcuti's and Dr. Thourani's counsel, Mr. Robison, a "care package" of certain public materials and a confidential white paper Edwards submitted to the FTC arguing that the FTC should not bring this suit.[598] Edwards is paying Dr. Chetcuti's and Dr. Thourani's legal fees for this litigation, a fact that was not disclosed despite it being responsive to the FTC's subpoenas.[599] Dr. Chetcuti told Edwards's lawyers that he "would be very happy to help in any way I can or [Edwards] would need," which included his testimony in the hearing.[600]

XIII. The Equities Favor a Preliminary Injunction

A. Legal Standard

233. The second step in determining whether to grant preliminary relief is to "weigh the equities in order to decide whether enjoining the merger would be in the public interest." *IQVIA*, 710 F.Supp.3d at 400 (quoting *Penn State Hershey*, 838 F.3d at 352); 15 U.S.C. § 53(b).

234. In enacting Section 13(b), "Congress further demonstrated its concern that injunctive relief be broadly available to the FTC by incorporating a unique 'public interest' standard in 15 U.S.C. § 53(b), rather than the more stringent, traditional 'equity' standard for injunctive relief." *FTC v. Exxon Corp.*, 636 F.2d 1337, 1343 (D.C. Cir. 1980). "The equities will often weigh in favor of the FTC, since 'the public interest in effective enforcement of the

[597] Chetcuti Day 6-AM 28:2-13; 28:25-29:16; Thourani Dep. 145:2-146:18, 148-15:150:8, 152:9-153:7; Vahl Day 4-AM 50:21-52:13.
[598] Decl. of Laura R. Hall Ex. X, Nov. 3, 2025 [*hereinafter* "Hall Decl."], Dkt. No. 108-4, ("care package"); Hall Decl. Ex. O, Dkt. No. 108-4 (white paper).
[599] Hall Decl. Ex. M, at 2, Dkt. No. 108-4; Hall Decl. Ex. N, at 1-2, Dkt. No. 108-4; PX0067; PX0069; Chetcuti Day 6-AM 46:23-47:8, 59:4-14, 61:17-23, 62:7-25.
[600] PX3097-003; Chetcuti Day 6-AM 51:12-21.

antitrust laws' was Congress's specific 'public equity consideration' in enacting the provision." *Whole Foods*, 548 F.3d at 1035 (quoting *Heinz*, 246 F.3d at 726). Hence, the FTC's demonstration "of likelihood of success creates a presumption in favor of preliminary injunctive relief." *Heinz*, 246 F.3d at 726.

235. Here, the FTC showed a "likelihood of success on the merits," *Sysco*, 113 F.Supp.3d at 22, and Defendants fail to rebut the FTC's case. The Court should grant a preliminary injunction because the FTC is likely to succeed on the merits, the equities weigh in favor of an injunction, and an injunction would be in the public interest. *See Heinz*, 246 F.3d at 714-15.

236. In assessing the equities, courts "consider whether the *injunction,* not the *merger*, would be in the public interest." *Penn State Hershey*, 838 F.3d at 353. Defendants' claimed merger benefits are therefore not cognizable public equities. Moreover, while denying a preliminary injunction may prevent the FTC from "recreat[ing] pre-merger competition," *Heinz*, 246 F.3d at 726, entering an injunction is not fatal to private efficiencies, as defendants can consummate the merger if they prevail in the FTC's administrative adjudication. *Penn State Hershey*, 838 F.3d at 353 ("We see no reason why, if the merger makes economic sense now, it would not be equally sensible to consummate the merger following a FTC adjudication on the merits that finds the merger lawful.").

237. Several courts have rejected public equities claims based on asserted efficiencies that fail the efficiencies standard. *See, e.g.*, *Wilhelmsen*, 341 F.Supp.3d at 74 ("Given the court's finding that Defendants' claimed efficiencies cannot be independently verified, the court cannot conclude on this record that those efficiencies outweigh the potential harm to the public resulting from further consolidation in the MWT industry."); *Cardinal Health*, 12 F.Supp.2d at 62-63; *FTC v. Kroger Co.*, 2024 WL 5053016, at *38 (D. Or. Dec. 10, 2024). This Court should do the same.

238. Courts recognize the public interest in avoiding "scrambling of the eggs," which may cause irreparable harm. *Whole Foods*, 548 F.3d at 1034; *Sysco*, 113 F.Supp.3d at 87 (FTC may face the "daunting and potentially impossible task of 'unscrambling' the eggs" if the merger is ultimately deemed unlawful). The inherent difficulties of divesting integrated assets after a merger has been consummated weigh in favor of injunctive relief. *Whole Foods*, 548 F.3d at 1034; *accord FTC v. Dean Foods Co.*, 384 U.S. 597, 606 n.5 (1966); *cf.* 15 U.S.C § 21(b) (FTC "shall issue . . . an order requiring such person to . . . divest" the acquired assets upon administrative finding that a transaction violated Section 7). Divestiture cannot remedy the harm if the Proposed Transaction is allowed to proceed but is later found illegal, because "[a]t best, divestiture is a slow, cumbersome, difficult, disruptive and complex remedy." *FTC v. Lancaster Colony, Corp.*, 434 F.Supp. at 1088, 1096 (S.D.N.Y. 1977) ; *accord Heinz*, 246 F.3d at 726 (recognizing that "divestiture is an inadequate and unsatisfactory remedy in a merger case").

B. Edwards Planned to Cancel the ARTIST Trial

239. Public equities support the continuation of the ARTIST trial to expand Trilogy's indication to patients at low or intermediate surgical risk and give them a non-surgical option.

240. Shortly after Edwards acquired JC Medical and agreed to acquire JenaValve, evidence shows that one of Edwards' "Key Priorities for 2024-2025" was "[n]ot proceed with the ARTIST [trial],"[601] and in its 2024 New Product Development Annual Operating Plan, Edwards included ARTIST on a list of programs it planned to cancel.[602] On August 1, 2024, Edwards' SVP for THV Marketing and Strategy emailed the Edwards executive responsible for TAVR-AR integration seeking guidance on if they could inform JenaValve that Edwards "[has] a preference

[601] PX1280-001; Concepcion Day 3-PM 9:18-23, 12:6-12.
[602] Sharma Day 5-PM 146:15-147:21; PX1512-001.

not to continue their ARTIST IDE" and how he thought JenaValve might respond.[603]

241. Edwards failed to identify a single document that suggests they will continue ARTIST in the future, and even in self-serving testimony, Edwards executives did not identify actual budget plans to finance the program. Even if they suddenly committed to doing so, as Mr. Zovighian testified, commitment to invest in R&D today is not a commitment to invest in the future.[604] This is consistent with Mr. Kilcoyne's testimony that no one at Edwards has promised to continue with ARTIST.[605]

C. Edwards Planned to Cancel the Large Valve Program

242. Edwards may not pursue development of the larger Trilogy valve sizes if the Proposed Transaction is consummated. As discussed in Section X.C.1, JenaValve is developing a larger valve size for Trilogy and plans to expend significant effort on the program if the proposed transaction terminates.[606] However, because J-Valve already has large valve sizes and because developing large-diameter valves is difficult, Edwards has yet to determine whether it will continue JenaValve's large valve program.[607] Dr. Pinto confirmed that no one at Edwards has made any promises to continue the JenaValve large valve program.[608]

243. Edwards claims it is acquiring both JC Medical and JenaValve to treat a broader set of patients, but it would not need J-Valve if it continued development of larger Trilogy valves.[609]

D. Edwards Knew of the Antitrust Risk of Acquiring Both Companies

244. Edwards' concealing the simultaneous acquisition of JC Medical from JenaValve has

[603] Sharma Day 5-PM 145:13-146:4; PX1192-001.
[604] Zovighian Day 2-PM 53:8-21, 54:24-55:2
[605] Kilcoyne Day 1-AM 113:22-114:3.
[606] Kilcoyne Day 1-AM 115:19-24; Kilcoyne Day 1-PM 4:19-5:1.
[607] Bobo Day 3-AM 32:20-33:23; Bierman Day 3-AM 87:23-88:1.
[608] Pinto Day 4-AM 9:20-23.
[609] Bobo Day 3-AM 34:9-35:23.

stirred animosity and distrust at JenaValve.[610]

245. After the FTC filed its complaint in the present litigation, Mr. Zovighian wrote in his personal notes that he "knew it was risky."[611]

246. Mr. Zovighian was concerned that JenaValve may sue Edwards if the acquisition does not go through, so he placed restrictions on how JenaValve could use money from Edwards to ensure that it could not be used to sue Edwards.[612]

E. Edwards Intentionally Hid Its Acquisition of JC Medical From the FTC

247. Edwards and Genesis agreed to a $115 million up-front payment to Genesis for JC Medical—$4 million below the 2024 HSR threshold.[613] At the same time, Edwards made an additional $25 million investment into Genesis to make up the valuation gap while keeping the JC Medical acquisition below $119 million to avoid making an HSR filing.[614]

248. Mr. Bobo told Mr. Kilcoyne that the JC Medical transaction was intentionally structured to be below the HSR threshold, but acknowledged that adding the Genesis equity investment to the upfront payment would have made the transaction reportable.[615] Despite testifying that the transactions were separate, Mr. Bobo himself described them as "a $25M investment in Genesis connected to the JC Medical transaction."[616] JC Medical, Genesis, and Edwards business executives and lawyers were "all aligned in avoiding HSR."[617]

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[610] *See supra* § III.
[611] Zovighian Day 2-PM 44:22-24, PX1437-001.
[612] Zovighian Day 2-PM 69:17-70:5.
[613] PX1039-001; Turco Day 4-AM 92:13-93:2.
[614] PX1039-001; Turco Day 4-AM 92:13-94:21; Zovighian Day 2-PM 49:23-50:2; *see, e.g.*, PX1545-001; PX1380-001; PX1069-002.
[615] PX1044-002; Bobo Day 2-PM 129:9-131:4, 131:23-134:4, 135:12-18.
[616] PX1069-002; Bobo Day 2-PM 135:19-136:8.
[617] PX1479-001.

249. Edwards avoided publicly disclosing that it acquired JC Medical.[618] Mr. Bobo asked Edwards' controller to get approval from Edwards' auditor to omit JC Medical's name from Edwards' SEC filings about the acquisition.[619] Mr. Bobo considered it "a win" for Edwards when JC Medical agreed not to name Edwards in its press release about its sale.[620]

250. Edwards reported to its Board of Directors, and Edwards' CEO conceded during the hearing, that the total consideration for the JC Medical acquisition was "115 million for JC Medical plus a 20 to 30 million investment in Genesis Medical."[621] Edwards did not disclose its $25 million investment in its 10-Q.[622]

F. Edwards Disregarded the Firewall and Shared JenaValve Confidential Information

251. Despite JenaValve requiring that Edwards impose a firewall between Edwards' employees and JenaValve's confidential information, many Edwards executives and personnel are not only aware of JenaValve's confidential FDA communications, including its most recent deficiency letter, but they have disclosed this information in open court.[623]

252. An Edwards employee who was permitted to access JenaValve's information sent nonpublic information about JenaValve's FDA application to Laksen Sirimanne in October 2024.[624] Mr. Sirimanne forwarded the information to the president of Edwards' TAVR division and the executive overseeing the J-Valve integration and proposed having a meeting to discuss the information.[625]

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[618] Wood Day 2-AM 30:20-23.
[619] Bobo Day 2-PM 137:13-20.
[620] Bobo Day 2-PM 137:6-12.
[621] Zovighian Day 2-PM 110:13-18 (referencing DX0109-003).
[622] Zovighian Day 2-PM 49:23-50:2, 110:2-6, 110:19-21.
[623] Bobo Day 2-PM 121:7-17; Day 1-AM 48:2-3 (EW Opening Arg.).
[624] Sirimanne Day 5-PM 101:6-8, 104:5-13; PX1243-001-004.
[625] Sirimanne Day 5-PM 104:14-105:3; PX1243-001.

Dated: December 10, 2025

Respectfully submitted,

/s/ Laura R. Hall

Daniel S. Guarnera
Director
Bureau of Competition

David Shaw
Principal Deputy Director
Bureau of Competition

Taylor C. Hoogendoorn
Deputy Director
Bureau of Competition

Laura R. Hall (N.Y. 4337408)
Barrett J. Anderson (D.C. 1024159)
Jordan S. Andrew (M.D. 0912150027)
James R. Weiss (N.Y. 4465209)
Lisa DeMarchi Sleigh (D.C. 485853)
Kendall Alford (D.C. 90028932)
Nathan Brenner (Ill. 6317564)
Habin Chung (D.C. 1048514)
Jacob Danziger (M.D. 1412160201)
Evan R. Johnson (D.C. 1722341)
Wade Lippard (D.C. 1616824)
Megan McKinley (N.Y. 5940432)
Betty Jean McNeil (D.C. 888230599)
Matthew E. Joseph (D.C. 1030157)
Dylan P. Naegele (D.C. 1670918)
Elena Ponte (N.Y. 5700877)
Catherine M. Sanchez (VA 75376)
William M. Segal (D.C. 1048390)
Michelle J. Seo (N.Y. 5007091)
Hilla Shimshoni (D.C. 1033015)
Varnitha Sivaprasad (N.Y. 5337670)
Jay Tymkovich (D.C. 241366)
Lily Verbeck (D.C. 90006809)
Nicholas A. Widnell (D.C. 439474)

Federal Trade Commission
Bureau of Competition
600 Pennsylvania Avenue, NW
Washington, D.C. 20580
Telephone: (202) 326-3282
Email: lhall1@ftc.gov

Counsel for Plaintiff
Federal Trade Commission

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 10th day of December 2025, I served the foregoing on the following counsel via email and the Court's CM/ECF system:

Joshua Lipton
Michael J. Perry
Jamie E. France
Stephanie Pearl
Logan Billman
Connor Leydecker
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

Ryan A. Shores
D. Bruce Hoffman
Jeremy J. Calsyn
Jacob M. Coate
Kelton Anderson
CLEARY GOTTLIEB STEEN & HAMILTON LLP
2112 Pennsylvania Avenue, NW
Washington, DC 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 Edwards Lifesciences Corp.

Jonathan Klarfeld
Michael S. McFalls
Samer M. Musallam
Elizabeth McInerney
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, DC 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
ROPES & GRAY LLP
800 Boylston Street
Boston, MA 02199
Telephone: (617) 951-7000
Email: Matthew.McGinnis@ropesgray.com

Counsel for JenaValve Technology, Inc.

/s/ Laura R. Hall
Laura R. Hall (N.Y. 4337408)
Federal Trade Commission
Bureau of Competition
600 Pennsylvania Avenue, NW
Washington, D.C. 20580
Telephone: (202) 326-3282
Email: lhall1@ftc.gov

Counsel for Plaintiff
Federal Trade Commission