IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

EDWARDS LIFESCIENCES CORPORATION,
One Edwards Way
Irvine, C.A. 92614

and

JENAVALVE TECHNOLOGY, INC.,
4 Cromwell, Suite 100
Irvine, C.A. 92618

Defendants.

Civil Action No.: 1:25-cv-2569

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

COMPLAINT

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys, petitions this Court for a preliminary injunction enjoining Edwards Lifesciences Corporation ("Edwards") and its subsidiaries, from consummating its proposed acquisition (the "Proposed Acquisition") of JenaValve Technology, Inc. ("JenaValve"). The Commission seeks this relief pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), and Section 16 of the Clayton Act, 15 U.S.C. § 26. Absent such relief, Edwards and JenaValve (collectively, "Defendants") will be free to consummate the Proposed Acquisition after 11:59 p.m. on August 6, 2025.

The Commission initiated an administrative proceeding, pursuant to Sections 7 and 11 of the Clayton Act, 15 U.S.C. §§ 18, 21, and Section 5 of the FTC Act, 15 U.S.C. § 45, by filing an administrative complaint on August 6, 2025. Pursuant to FTC regulations, the administrative proceeding on the merits will begin on January 7, 2026. The administrative proceeding will determine the legality of the Proposed Acquisition and will provide all parties a full opportunity to conduct discovery and present testimony and other evidence regarding the likely competitive effects of the Proposed Acquisition.

Plaintiff requires the aid of this Court to preserve the status quo and to protect competition during the pendency of the administrative proceeding. Allowing Defendants to consummate the Proposed Acquisition and combine their operations prior to a decision on the merits by the Commission through the administrative process would harm consumers and undermine the Commission's ability to remedy the anticompetitive effects of the Proposed Acquisition if it is ultimately found unlawful after a full trial on the merits and any subsequent appeals.

NATURE OF THE CASE

1. Edwards, a global supplier of medical devices for treating structural heart disease, proposes to acquire JenaValve, which is developing a transcatheter aortic valve replacement ("TAVR") device for the treatment of aortic regurgitation ("AR"), a potentially fatal heart condition. Through its subsidiary, JC Medical, Edwards is also developing a TAVR device for the treatment of AR ("TAVR-AR device"). Edwards and JenaValve are the only two companies that are currently conducting clinical trials on TAVR-AR devices in the United States. JenaValve expects to obtain approval from the U.S. Food and Drug Administration ("FDA") to commercialize its device by late 2025 or early 2026, and Edwards expects to obtain FDA

approval for its TAVR-AR device by the [redacted]. [redacted]. Thus, the Proposed Acquisition, if consummated, would consolidate the [redacted] TAVR-AR device [redacted] in the United States, eliminate the close and ongoing head-to-head competition between Edwards and JenaValve, and give Edwards a TAVR-AR monopoly for at least the next [redacted].

2. [redacted]—in a bold bid to [redacted]," Edwards executed agreements to acquire both JC Medical and JenaValve. [redacted] Edwards' gambit to acquire both companies, and their executives were [redacted]. JenaValve's Chief Commercial Officer [redacted] and its Senior Director of Strategy and Operations [redacted] Another JenaValve employee [redacted] JC Medical's Chief Executive Officer [redacted] Edwards, having consummated its JC Medical acquisition, now seeks to close its acquisition of JenaValve.

3. At least 8 million Americans over age 50 suffer from AR. AR is a serious and often fatal condition in which the heart's aortic valve does not close properly, causing blood to backflow into the heart. AR can cause heart failure and sudden cardiac death. Approximately one in four people diagnosed with severe and symptomatic AR will die within a year if left untreated.

4. Currently, the only FDA-approved treatment for AR is surgical valve replacement via open heart surgery, or surgical aortic valve replacement ("SAVR"). This procedure is not recommended for high-risk patients, including patients who are older, frailer or have certain co-morbidities. Aside from open heart surgery, there is no suitable treatment option available for people with AR. TAVR-AR devices fulfill this unmet need. This revolutionary technology is significantly less invasive than open heart surgery and offers a safe and effective treatment for AR.

5. JenaValve is poised to become [redacted]. JenaValve has [redacted] clinical trials for its device, called Trilogy, [redacted]. Edwards/JC Medical, which has an ongoing clinical trial for its J-Valve TAVR-AR system, is [redacted] and is expected to be [redacted]

6. JenaValve and JC Medical [redacted]. For example, to [redacted] Trilogy, JenaValve launched a large new pivotal trial called ARTIST aimed at showing that treatment with Trilogy is as effective as SAVR, which, if successful, would make Trilogy available to even more patients—those who are eligible for open heart surgery. JenaValve's Chief Marketing Officer [redacted] For its part, JC Medical sought to [redacted] to JenaValve. One doctor affiliated with JC Medical [redacted], to which JC Medical's founder and former CEO [redacted]

[redacted] In another conversation, the same doctor [redacted] JC Medical [redacted]

7. If Edwards controls both Trilogy and J-Valve, the pace of innovation in TAVR-AR devices is likely to slow and the risk of one of the valves being de-prioritized or abandoned rises.

8. For example, Edwards anticipated [redacted] after closing the Proposed Acquisition. Days after the agreement was signed, [redacted] and Edwards' Vice President of Clinical Affairs [redacted] The next day, an Edwards' Senior Vice President [redacted] JenaValve documents [redacted] if the Proposed Acquisition closes, while it [redacted] if the Proposed Acquisition fails to close. Should Edwards [redacted]

9. Edwards executives [redacted] and have not [redacted]

[redacted]. Edwards' CEO [redacted]

[redacted].

10. Edwards also would have little business reason to maintain two valves that treat the same indication. Documents indicate that it is likely to [redacted]. For example, [redacted] Alternatively, Edwards has [redacted].

11. The Proposed Acquisition would eliminate the vigorous head-to-head competition between Edwards/JC Medical and JenaValve, bringing under one roof the only two TAVR-AR companies conducting ongoing clinical trials with the FDA. The Proposed Acquisition therefore may substantially lessen competition or tend to create a monopoly in the TAVR-AR device market, resulting in reduced innovation, diminished product quality, and potentially increased prices for U.S. consumers.

12. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Proposed Acquisition. Defendants cannot demonstrate that new entry of TAVR-AR devices would be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition. Nor will Defendants be able to show sufficient cognizable, verifiable, or merger-specific efficiencies that would offset the likely and substantial competitive harm from the Proposed Acquisition.

JURISDICTION AND VENUE

13. The Proposed Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

14. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b); Section 16 of the Clayton Act, 15 U.S.C. § 26; and 28 U.S.C. §§ 1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action.

15. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part:

> Whenever the Commission has reason to believe
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public— the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond. . . .

16. Defendants, and each of their relevant operating entities, affiliates, and subsidiaries, are and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

17. Defendants transact business in the District of Columbia and are subject to personal jurisdiction therein. Defendant Edwards has an office at 601 Thirteenth Street NW, Washington, D.C., and its subsidiary JC Medical conducted clinical trials for the Early Feasibility Study for its J-Valve TAVR-AR device at, among other locations, a hospital in the

District. Defendant JenaValve also used the same District hospital as a site in the pivotal study for its Trilogy TAVR-AR device. On information and belief, [redacted]

18. At the Cardiovascular Research Technologies ("CRT") conference held annually in Washington DC, both JenaValve and Edwards/JC Medical gave presentations on their TAVR-AR devices to media and industry participants. At CRT the Defendants [redacted]. For example, at the 2023 CRT conference, JenaValve's CEO [redacted] JenaValve's marketing team attended J-Valve's presentation that year and [redacted] Before the 2024 CRT, JenaValve's Chief Commercial Officer [redacted]

19. The FTC Act, 15 U.S.C. § 53(b), authorizes nationwide service of process, and personal jurisdiction exists where service is effected pursuant to federal statute. Fed. R. Civ. P. 4(k)(1)(C). Venue is proper in this District under 28 U.S.C. § 1391(b) and (c), 15 U.S.C. § 22, and 15 U.S.C. § 53(b).

THE PARTIES AND THE PROPOSED ACQUISITION

20. Plaintiff, the Federal Trade Commission, is an agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 *et seq.*, with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The Commission is vested with authority and responsibility for enforcing, *inter alia*, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

21. Defendant Edwards is a Delaware corporation headquartered at One Edwards Way, Irvine, CA 92614. Edwards is a global structural heart medical device manufacturer. Edwards agreed to acquire JC Medical on [redacted]. JC Medical owns J-Valve, a TAVR device designed to treat AR. Edwards/JC Medical is currently conducting a pivotal trial to support FDA approval of J-Valve (which Edwards [redacted]) and anticipates receiving FDA approval in [redacted].

22. Prior to acquiring JC Medical and agreeing to acquire JenaValve, Edwards [redacted]. Edwards [redacted] deciding to acquire the two companies.

23. Defendant JenaValve is a medical device company developing TAVR systems for the treatment of aortic valve disease. It is headquartered in Irvine, California. JenaValve's flagship product, Trilogy, is a TAVR device designed to treat AR.

24. JenaValve published the results of its pivotal trial for Trilogy, ALIGN-AR, in March 2024 and [redacted] It expects to receive FDA approval for Trilogy [redacted]

25. Pursuant to its Agreement and Plan of Merger with JenaValve, executed on [redacted] Edwards proposed [redacted] JenaValve for approximately [redacted].

26. The competitive harms in this case result from Edwards owning *both* JC Medical *and* JenaValve. As early as [redacted].

27. JenaValve itself [redacted] The JenaValve CEO's [redacted].

28. On August 6, 2025, by a 3-0 vote, the Commission found reason to believe that the Proposed Acquisition would substantially lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. On August 6, 2025, the Commission commenced an administrative adjudication

proceeding to determine whether the Proposed Acquisition is unlawful. An administrative trial before an Administrative Law Judge, is scheduled to begin on January 7, 2026. The ongoing administrative trial provides a forum for all parties to conduct discovery, followed by a merits trial with up to 210 hours of live testimony. *See* 16 C.F.R. § 3.41. The decision of the Administrative Law Judge is subject to appeal to the full Commission, which, in turn, is subject to judicial review by a United States Court of Appeals.

29. In authorizing the filing of this complaint, the Commission has determined that (1) it has reason to believe the Proposed Acquisition would violate the Clayton Act and the FTC Act by substantially lessening competition or tending to create a monopoly in one or more lines of commerce, and (2) an injunction of the Proposed Acquisition pending the resolution of the Commission's administrative trial and any appeals will promote the public interest to minimize harm to patients, customers and the American public, and to preserve the Commission's ability to grant an adequate remedy if it concludes, after the administrative trial, that the Proposed Acquisition is unlawful.

INDUSTRY BACKGROUND

30. TAVR is a transformative technology that allows physicians to safely and effectively replace malfunctioning aortic valves without the need for SAVR, i.e. open heart surgery. TAVR allows a physician to use a catheter to guide an artificial valve through a patient's blood vessel, typically the femoral artery, and place the artificial valve in the position of the malfunctioning native valve. The replacement valve then expands and anchors securely, taking over the native aortic valve's task of regulating blood flow. Compared to SAVR, TAVR is a much less invasive procedure and only requires a small incision in the patient's groin. The physician does not need to stop the patient's heart or administer general anesthesia. Conversely,

SAVR requires the use of general anesthesia, surgically opening the patient's chest, stopping the patient's heart, and replacing the patient's valve with a new mechanical or bioprosthetic valve. TAVR patients experience much shorter recovery times compared to SAVR. Most TAVR patients spend one day in the hospital after the procedure, compared to three to seven days following SAVR.

31. TAVR devices are already commercially available for other heart valve diseases. Edwards commercialized the first TAVR device to treat aortic stenosis ("AS") ("TAVR-AS device") when it debuted its Sapien valve in 2011. AS is characterized by a buildup of calcium on the aortic valve, preventing it from fully opening after each heartbeat and impeding blood flow. Whereas AR is caused by the aortic valve's failure to close after each heartbeat, AS is caused by the aortic valve's failure to open fully due to calcification. Treatment with the use of TAVR-AS devices has become a multibillion-dollar market, and Edwards remains the overwhelming market leader, [redacted] of the TAVR-AS market.

32. The JenaValve and JC Medical TAVR-AR devices are designed specifically to adhere to AR patients' aortic annuli. The aortic annulus is the ringed juncture that acts as the foundation for the attachment of the aortic valve.



33. Trilogy and J-Valve use self-expanding frames that deploy in the heart and anchor to the aortic annulus. Once positioned, the TAVR-AR device takes over the task of regulating the patient's blood flow.

34. TAVR-AR devices are Class III medical devices. The FDA must grant the device PMA approval before the device may be sold commercially. PMA approval is based on the FDA's determination that the PMA application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. To generate this scientific evidence, medical device companies will first conduct early feasibility studies to assess the initial safety and functionality of a device. After a successful early feasibility study, the medical device company will conduct pivotal trials, typically involving hundreds of patients, which demonstrate the safety and efficacy of the device for its intended use in support of a PMA application. These clinical trials take years to complete and can cost tens of millions of dollars.

THE RELEVANT ANTITRUST MARKET

A. TAVR-AR Devices Is the Relevant Product Market

35. A relevant product market in which to assess the competitive impact of the Proposed Acquisition is TAVR-AR devices.

36. TAVR-AR devices are designed specifically to treat AR and have unique characteristics that afford them distinct safety and efficacy profiles compared to other medical devices. Defendants, the medical community, and other industry participants recognize dedicated TAVR-AR devices as having unique uses for which there are no adequate alternatives. Only a small number of companies have created TAVR-AR devices for use in the United States, and [redacted]. Competition between TAVR-AR device competitors that are in their clinical trial stages drives improvements in their research, development, and commercialization efforts—ultimately benefitting doctors and patients.

37. AR's unique anatomical characteristics require dedicated transcatheter treatment devices. TAVR-AS devices are unsuitable treatments for patients with AR. AS involves calcified aortic leaflets that do not fully open; AR involves uncalcified leaflets that do not close properly. TAVR-AS devices are designed to rely on the calcium deposits in stenotic valves to anchor themselves and therefore may not anchor securely to patients with AR if those patients do not have similar calcium buildup.

38. Doctors have attempted off-label use of TAVR-AS devices to treat AR but have found there is significant risk the valve dislodges, resulting in a potentially fatal issue called "embolization." For this reason, Defendants [redacted] TAVR-AR devices, in contrast, are designed specifically for treating AR, affixing to non-stenotic aortic valves without

calcium deposits. The structural heart industry and medical community similarly recognize that TAVR-AS devices are not viable substitutes for dedicated TAVR-AR devices.

39. TAVR-AR devices are designed to treat a distinct patient population—patients with AR—and they are the only available treatment for patients who are ineligible for SAVR due to age or other co-morbidities. Further, the interventional cardiologists who use TAVR-AR devices are often different than the cardiac surgeons who implant aortic valves through open heart surgery.

B. The United States Is the Relevant Geographic Market

40. The United States is the relevant geographic market to assess the competitive effects of the Proposed Acquisition. TAVR-AR customers cannot practically turn to a TAVR-AR device provided outside the United States.

41. TAVR-AR devices require approval by the FDA to receive reimbursement from healthcare payers in the United States. As such, TAVR-AR devices sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

C. Market Structure

42. Edwards/JC Medical and JenaValve are the only two competitive participants in the TAVR-AR device market. According to JC Medical, [redacted] JenaValve's [redacted]. For example, a JenaValve [redacted] Other party documents [redacted]

43. A third company, Laguna Tech, is a small developer [redacted] It has a [redacted] TAVR-AR product that is [redacted]

Defendants' devices in development. Moreover, Laguna Tech [redacted]. JenaValve, [redacted]

44. No TAVR-AR company other than Edwards/JC Medical and JenaValve is engaged in clinical trials in the United States. There are TAVR-AR companies in various stages of development outside the United States, but to enter the United States market those companies would have to satisfy the full slate of FDA clinical trials, a process that typically takes at least five years.

45. The merging parties combine to account for [redacted], of the TAVR-AR device market, which is currently in its clinical trial stage. Further, given Trilogy's [redacted], JenaValve is anticipated to maintain 100% of commercial sales of TAVR-AR devices until J-Valve's [redacted], at which point the companies will split the market for the [redacted].

46. Should the Proposed Acquisition be consummated, the number of competitors in the TAVR-AR device market would shrink from two to one.

ANTICOMPETITIVE EFFECTS OF THE PROPOSED ACQUISITION

47. The Proposed Acquisition would substantially lessen competition or tend to create a monopoly in the TAVR-AR device market in the United States by eliminating vigorous head-to-head competition between Edwards/JC Medical and JenaValve, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

48. Defendants do not [redacted]. For example, [redacted]:

[redacted]

49. Edwards/JC Medical and JenaValve consistently identify [redacted] In a [redacted] Likewise, JenaValve's Chief Commercial Officer [redacted] In another instance, JenaValve's Director of Marketing [redacted] JenaValve similarly recognized [redacted]

[redacted] The current head-to-head competition between Edwards/JC Medical and JenaValve drives the companies to accelerate the advancement and improvement of their TAVR-AR devices more than they would absent that competition. [redacted], industry participants identify Edwards/JC Medical and JenaValve as the only two companies with advanced TAVR-AR device programs that are in FDA clinical trials.

50. As direct competitors, Edwards/JC Medical and JenaValve have spurred each other to accelerate and advance their TAVR-AR devices. JC Medical emphasized that [redacted] and they [redacted] JenaValve [redacted] as one JenaValve employee [redacted] For example, due to competitive pressure from JC Medical, JenaValve [redacted]. In [redacted], JenaValve's Chief Medical Officer [redacted]." A few months later, in [redacted], JenaValve's Chief Commercial Officer reacted to [redacted] A few days later, JenaValve leadership evaluated [redacted]. JenaValve's Director of Strategy and Field Operations wrote, [redacted]

[redacted] If JenaValve's ARTIST trial is successful, thousands more patients with severe AR will have access to Trilogy.

51. Additionally, [redacted], which will expand patient access to the Trilogy valve system. When JenaValve [redacted] As JenaValve was running its ALIGN pivotal trial, [redacted]. Many of those patients received [redacted] JenaValve concluded that [redacted] It recognized that it [redacted] Soon after, JenaValve concluded [redacted] Contemporaneously, JenaValve's Chief Commercial Officer recognized that there would be [redacted]

52. After Edwards agreed to acquire JenaValve, however, [redacted]

[redacted]



Thus, if the Proposed Acquisition closes, JenaValve anticipates [redacted] If the Proposed Acquisition terminates, however, JenaValve expects [redacted] Even more concerning, Edwards documents indicate that it would [redacted] Elsewhere, Edwards stated that [redacted]



53. Patients will suffer if ongoing competition between Edwards/JC Medical and JenaValve ceases, and [redacted] post-acquisition.

54. Edwards/JC Medical and JenaValve also compete head-to-head to place their TAVR-AR devices in clinical trial sites at major medical research institutions, where they generate quality clinical data for FDA approval. In addition, they compete for the best TAVR specialists to serve as principal investigators for their clinical trials. For example, JenaValve's Director of Marketing noted in [redacted] Around the same time, JenaValve's Chief Commercial Officer [redacted]

55. There is robust and ongoing competition between Edwards/JC Medical and JenaValve to improve the quality of their TAVR-AR devices and generate superior clinical outcomes. For example, one risk of TAVR-AR procedures is the potential to disrupt the heart's conduction system, requiring the implantation of a pacemaker in addition to the new valve. All else equal, a TAVR-AR device with a lower "pacemaker rate"—the percentage of TAVR-AR procedures requiring pacemaker implantation—is considered superior. Currently, [redacted]. In part due to [redacted] and that it had [redacted] JenaValve recognizes [redacted]. JenaValve's Director of Marketing commented on an [redacted]

[redacted] Prior to an industry conference JenaValve's CEO predicted that [redacted] and directed employees to [redacted]

56. With both valves in its portfolio, Edwards may choose to mothball or phase out Trilogy or J-Valve. As one JenaValve employee remarked [redacted] An Edwards [redacted] Even if Edwards [redacted] and continues to offer both devices, it would have little incentive to maintain the current competitive interaction between the two devices.

COUNTERVAILING FACTORS DO NOT OFFSET THE PROPOSED ACQUISITION'S THREAT TO COMPETITION

57. Defendants cannot demonstrate that entry of other TAVR-AR device companies would be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition.

58. Defendants cannot demonstrate that the Proposed Acquisition would likely generate verifiable, cognizable, merger-specific efficiencies that would offset the likely and substantial competitive harm from the Proposed Acquisition.

VIOLATION

COUNT I – ILLEGAL ACQUISITION

59. The allegations of Paragraphs 1 through 58 above are incorporated by reference.

60. The Proposed Acquisition, if consummated, may substantially lessen competition or tend to create a monopoly in the TAVR-AR device market in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

LIKELIHOOD OF SUCCESS ON THE MERITS, BALANCE OF EQUITIES, AND NEED FOR RELIEF

61. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission, whenever it has reason to believe that a proposed acquisition is unlawful, to seek preliminary injunctive relief to prevent consummation of the acquisition until the Commission has had an opportunity to adjudicate the acquisition's legality in an administrative trial. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities. The principal public equity weighing in favor of issuance of preliminary injunctive relief is the public interest in effective enforcement of the antitrust laws. Private equities affecting only Defendants' interest cannot defeat a preliminary injunction.

62. The Commission is likely to succeed in proving that the effect of the Proposed Acquisition may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, or Section 5 of the FTC Act, 15 U.S.C § 45. In particular, the Commission is likely to succeed in demonstrating, among other things, that:

a. The Proposed Acquisition would have anticompetitive effects in the United States, in a relevant product market of TAVR-AR devices;

b. Substantial and effective entry or expansion is difficult and would not be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition; and

c. The efficiencies and procompetitive benefits asserted by Defendants do not justify the Proposed Acquisition.

63. Preliminary relief is warranted and necessary. Should the Commission rule, after the full administrative trial that the Proposed Acquisition is unlawful, reestablishing the status quo ante if the Proposed Acquisition has already occurred in the absence of preliminary relief would be extremely difficult. Moreover, in the absence of relief from this Court, substantial harm to competition would likely occur in the interim, even if suitable divestiture remedies were obtained later.

64. Accordingly, the equitable relief requested here is in the public interest. Wherefore, the Commission respectfully requests that:

a. Edwards and JenaValve be preliminarily enjoined from taking any further steps to consummate the Proposed Acquisition and any related transactions, stock assets, or acquisition of any other interests of one another either directly or indirectly; carrying out any other agreement, understanding, or plan by which Edwards would acquire control over JenaValve or any of its assets;

b. Retain jurisdiction and maintain the status quo until the administrative trial that the Commission has initiated is concluded; and

c. Award such other and further relief as the Court may determine is appropriate, just, and proper.

Dated: August 6, 2025

Respectfully submitted,

/s/ Barrett J. Anderson

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