IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DISTRICT OF COLUMBIA

Federal Trade Commission, *Plaintiff*, v. Edwards Lifesciences Corporation, and JenaValve Technology, Inc., *Defendants*.	Case No. 1:25-cv-02569-RC Judge Rudolph Contreras

DEFENDANTS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

REDACTED

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PROPOSED FINDINGS OF FACT

I. Background

A. Edwards is the leader in heart-valve innovation, JenaValve is a struggling startup.

1. Edwards Lifesciences is the leader in structural heart-valve technology. *See* 11/20 AM (Bobo) 7:2–8. Such technology is complex and must receive FDA approval before it may be sold commercially in the US. 11/19 PM (Zovighian) 88:3–6; 11/19 AM (Wood) 58:6–11. The FDA-approval process is itself unpredictable and fraught with "unforeseen complications . . . that require companies to go back and make redesigns," extending the timeline for approval. 11/21 AM (Vahl) 23:15–19.

2. Founded in 1958, Edwards developed the world's first artificial heart valve. 11/19 PM (Zovighian) 86:10–13. Edwards subsequently pioneered transcatheter and surgical therapies for aortic-valve disease, including surgical artificial valve replacement ("SAVR") for aortic stenosis ("AS"). Edwards then began working on a Transcatheter Aortic Valve Replacement ("TAVR") therapy for AS patients. *Id*. at 86:14–17. TAVR is a minimally invasive procedure in which a new valve is inserted through a catheter to replace the old defective valve. DX-0288 (McWilliams Rep.) ¶ 17; *see* 11/21 AM (Vahl) 15:7–15. In 2003, Edwards acquired a small, foreign startup (PVT) and combined its R&D stream with Edwards' own R&D stream. 11/19 AM (Wood) 62:2–63:2. At the time of the acquisition, this was a "'bet the company' sort of decision." *Id.* at 63:24–25. Notably, even though other US strategics were on PVT's Board of Directors, only Edwards was willing to take a chance on TAVR-AS. *Id.* at 64:1–3.

3. By combining PVT's first-in-human clinical experience with Edwards' valve experience, the company "massively accelerate[d]" development. 11/19 AM (Wood) 63:3–10. This culminated in SAPIEN, the first commercially available TAVR-AS device in the US, which received FDA approval in 2011. 11/24 PM (Sharma) 120:9–13. Despite industrywide skepticism

about the viability of the TAVR-AS opportunity, Edwards successfully "built the [TAVR-AS] market" through continuous investment in technology iteration, clinical-evidence generation, and patient education. *Id*. at 140:1–14.

4. After receiving commercial approval for SAPIEN, Edwards has continued to innovate. 11/25 AM (Bailey) 151:11–19. It has subsequently developed five generations of SAPIEN—with a sixth valve currently in clinical trials and a seventh under development—each of which has been safer and more effective than the last. *See* 11/20 AM (Bierman) 93:3–25; DX-0191 at 21; 11/24 AM (Sirimanne) 59:3–8 (discussing DX-0211 at 9). Indeed, through these innovations, the mortality rate for SAPIEN has dropped from around 50% to less than 1%. 11/20 AM (Bierman) 94:1–17.

5. Edwards has also pursued clinical trials involving over 10,000 patients to expand "indications" (*i.e.*, the groups of patients that Edwards' devices can treat). DX-0220 at 6; 11/25 AM (Chetcuti) 18:20–19:8; 11/19 AM (Wood) 68:2–12 (discussing DX-0220 at 6). Today, Edwards has treated over 1 million AS patients. 11/20 AM (Bierman) 91:13–15; DX-0191 at 22. And, thanks to Edwards' efforts, TAVR-AS is now a multi-billion-dollar market. 11/25 AM (McWilliams) 102:19–103:7; 11/19 AM (Wood) 74:12–13.

6. Overall, Edwards has thousands of R&D engineers, hundreds of field technicians, and over 9,000 manufacturing employees. 11/19 PM (Zovighian) 81:5–10; DX-0211 at 6. It has extensive in-house valve-testing resources, cross-business Centers of Excellence, and expansive field clinical support to train and guide physicians. 11/19 AM (Wood) 108:12–24; 11/24 PM (Sirimanne) 46:3–4; 11/19 PM (Zovighian) 104:12–18. Edwards' sole focus is structural heart therapies, 11/19 PM (Zovighian) 87:21–88:1, and "[t]here isn't another TAVR manufacturer that exists today that has as much experience as [Edwards]." 11/20 AM (Bierman) 91:5–6.

7. Founded in Germany in 2006, 11/24 AM (Keltjens) 117:14–16, JenaValve is a small startup with about 12 R&D engineers, 12 sales employees, and 8 marketing employees, 11/18 PM (Kilcoyne) 123:16–124:8; 11/20 PM (Pinto) 151:11–23.

8. JenaValve [redacted] per year, does not expect to [redacted] (at best), and is currently subsisting on interim funding from Edwards. 11/18 PM (Kilcoyne) 45:2–15, 122:4–20.

9. JenaValve's sole product is Trilogy, a TAVR-AR therapy with commercial approval in Europe. DX-0288 (McWilliams Rep.) ¶ 28. As discussed further below, JenaValve has faced persistent quality and scaling issues that have crippled JenaValve's efforts to commercialize Trilogy at scale in Europe and repeatedly delayed FDA approval in the United States. *See* 11/18 PM (Kilcoyne) 113:6–114:4; 11/19 AM (Wood) 109:15–19; 11/20 AM (Bierman) 103:7–15. Innovating the current technology is beyond JenaValve's limited capabilities. 11/20 PM (Pinto) 151:24–152:10; 11/25 AM (Chetcuti) 11:22–12:2.

B. Aortic regurgitation is a deadly disease, and many companies are working on a TAVR therapy.

10. Like AS, aortic regurgitation ("AR") is a deadly disease of the aortic heart valve. 11/19 AM (Wood) 77:10–78:3; 11/20 PM (Pinto) 126:18–20. Approximately 10% of the US population with an aortic disease has AR. 11/20 PM (Pinto) 132:19–21. For patients with severe symptomatic AR—an advanced form of the disease afflicting over 100,000 Americans—nearly one in four patients die within one year of diagnosis without treatment. *Id*. at 126:18–20.

11. AR is chronically underdiagnosed and many patients go untreated, often due to a lack of options. 11/20 PM (Pinto) 131:1–2; 11/20 PM (Sun) 67:20–22. Today, in the US, SAVR is the only FDA-approved treatment for AR. 11/20 AM (Bierman) 83:20–84:1. SAVR can be effective for many patients, particularly those with low or intermediate surgical risk. 11/21 AM

(Pinto) 6:2–9; 11/20 PM (Pinto) 142:2–6, 144:6–11. But it is a poor option for higher risk patients. 11/18 PM (Kilcoyne) 85:9–17.

12. Edwards is currently working on a precommercial TAVR-AR device called SOJOURN. Edwards obtained SOJOURN (formerly J-Valve) through its acquisition of JC Medical, a small Chinese startup, in July 2024.

13. In addition to JenaValve, numerous other companies across the world are working on developing TAVR-AR devices including: Laguna Tech, Cuspa, MicroPort, KOKA Lifesciences, Jenscare, Shanghai Kindly (INT Medical), SAT, Vickor Medical, and Venus MedTech. DX-0228 at 8–9; DX-0197 at 15; 11/19 AM (Wood) 94:21–24 (discussing DX-0228 at 8–9); 11/20 AM (Bierman) 106:18–107:3 (discussing DX-0197 at 15); [redacted]. Edwards considers all of these companies to be part of the TAVR-AR "Competitive Landscape." DX-0197 at 15. Indeed, Jenscare already has commercial approval for its TAVR-AR device in China, and is actively in US clinical trials with a heart valve therapy developed in China. 11/20 AM (Bierman) 107:8–108:14. Further, Jenscare has previously brought a heart valve technology—a tricuspid valve device—that it developed in China to the United States. *Id.* at 108:6–16.

14. Also, large strategics in the structural-heart space—like Abbott, Medtronic, Boston Scientific, and Johnson & Johnson—could acquire any of the numerous TAVR-AR devices in development, or may develop a TAVR-AR device of their own. [redacted] This "fast follower" approach is a hallmark of competition in the structural-heart space. 11/21 PM (Kesselheim) 82:14–22, 83:17–84:16; [redacted]

15. Given the confidential nature of R&D work, there may be more non-public TAVR-AR devices in development. 11/19 AM (Wood) 92:8–23; 11/20 AM (Bierman) 106:23–107:7. For example, [redacted]. *Id.* at 83:3–6, 83:24–84:4.

16. Should a large strategic company acquire or launch a competing program, it could accelerate the clinical development and "catch up very quickly." 11/25 AM (Chetcuti) 24:7–19; *see also* 11/25 AM (McWilliams) 76:16–77:19.

C. Edwards agreed to purchase JenaValve to develop a TAVR-AR therapy, not to insulate itself from competition.

17. Given the close adjacency with AS—and the lack of options for inoperable and high-risk patients—Edwards is seeking to develop a TAVR device that can treat AR. *See* 11/19 AM (Wood) 78:21–79:1; 11/20 AM (Bobo) 54:25–55:5. As Edwards' CEO, Bernard Zovighian, testified, developing a TAVR-AR device is a "top priority." 11/19 PM (Zovighian) 95:17–20. This is what spurred Edwards' interest in JenaValve and its Trilogy device.

18. Serious negotiations with JenaValve began in October 2023, after JenaValve presented compelling data from its completed pivotal trial for inoperable and high-risk patients (ALIGN-AR). 11/19 AM (Wood) 79:14–80:6; 11/19 PM (Zovighian) 91:8–17. As negotiations continued into spring 2024, Edwards conducted due diligence into JenaValve, which revealed several material risks, previewed here and detailed further below.

19. *First*, and as discussed further below, JenaValve had significant issues with "manufacturing and scalability." 11/24 PM (Sharma) 132:10–16. The cost associated with each

valve sold was "astronomical." 11/20 AM (Bierman) 102:24–103:2. The percentage of usable valves was below 50%. *Id.* at 103:3–15. And JenaValve could not explain the gap between its anemic output and its optimistic future sales projections. *Id.* at 103:16–104:6; *see id.* at 104:11–21 (testifying that JenaValve's "rosy" projections were unsurprising for a startup looking to be acquired).

20. *Second*, to demonstrate to the FDA that an artificial valve will be sufficiently durable, companies must conduct accelerated wear testing ("AWT") to show that the valve can successfully complete 200 million cycles. 11/18 PM (Kilcoyne) 112:8–11. This is "required for FDA approval." *Id.* at 112:13. But during diligence, Edwards learned that JenaValve had "AWT durability testing failures." 11/24 PM (Sharma) 132:10–16. As discussed below, [redacted]

21. Despite these issues, Edwards believed that it could use its TAVR-AS experience and superior resources and capabilities to resolve JenaValve's problems and provide the best chance to obtain approval for, and successful commercialization of, Trilogy. 11/19 AM (Wood) 115:18–116:3. Thus, Edwards agreed to acquire JenaValve in July 2024 (the "Transaction"). *Id.* at 80:16–18. The merger agreement's termination date is January 23, 2026. PX-1166 at 107.

22. [redacted]; DX-0065 at 1; DX-0143. As Dr. Thourani, a National Principal Investigator for JenaValve's ALIGN Trial, put it: "[I]f somebody else was gonna buy [JenaValve], they would have bought it five years ago, six years ago, seven years ago, but they ain't." Thourani Dep. 124:12–14.

23. While Edwards was negotiating with JenaValve, a small Chinese startup (JC Medical) reached out to Edwards "out of the blue," to see if Edwards would be interested in acquiring it. 11/19 AM (Wood) 80:19–81:6; *see id.* at 79:14–80:6; 11/19 PM (Zovighian). 49:10–18. Like many companies, JC Medical had also been working on a TAVR-AR device (then-called J-Valve), but its Chinese parent was going to shut the project down imminently if JC Medical could not find outside investment. 11/21 AM (Turco) 80:13–19, 104:16–105:10, 106:19–22; DX-0123 at 1.

24. As Edwards CEO Bernard Zovighian explained: "JC Medical [was] a very small project. JenaValve [was] a company." 11/19 PM (Zovighian) 49:17–18.

25. JC Medical had developed promising long-term data in China. 11/21 AM (Turco) 100:3–11; 11/19 PM (Zovighian) 93:7–11. And J-Valve differed from Trilogy in several important ways, 11/19 AM (Wood) 83:12–21; *see also* DX-0078 at 1. Thus, Edwards saw J-Valve as an opportunity to develop a complementary device that could treat a broader patient population and yield better outcomes. 11/24 PM (Sharma) 139:7–16; 11/19 PM (Zovighian) 79:21–80:13, 90:20–91:3. In acquiring and combining two R&D streams, Edwards also expects to combine the learnings from each to increase the chance of FDA approval and improve the likelihood of developing successful next generation devices, just as it did in TAVR-AS. *See* 11/20 AM (Bobo) 31:9–32:13; 11/24 PM (Sirimanne) 97:20–98:21; 11/19 AM (Wood) 99:23–100:13 (discussing DX-0116 at 2).

26. In July 2024, Edwards acquired JC Medical and saved its technology from extinction. 11/19 AM (Wood) 80:16–81:6. Because JC Medical was in a very early stage and was about to be shut down, Edwards only paid for JC Medical a fraction of what it paid for JenaValve. *See* 11/19 PM (Zovighian) 48:17–24. Although the purchase price was *financially* "immaterial,"

JC Medical's *strategic importance* was not. *Id.* at 95:9–16. For example, Mr. Zovighian testified in response to a question from the Court that JC Medical "gave [Edwards] the opportunity to be able to treat more patients" and without both devices, Edwards could likely only treat "a subset of patients and not all of them." *Id.* at 79:16–80:13. And the combination of R&D streams, as discussed previously, would advance innovation.

27. JC Medical had also reached out to the US strategics—[redacted]—about a potential acquisition but none were interested. 11/21 AM (Turco) 85:12–86:6, 107:25–108:7; DX-0078; DX-0094. Dr. Turco also reached out to over 20 venture-capitalist and private-equity groups about funding for JC Medicals' pivotal trial, but these efforts, too, were unsuccessful. 11/21 AM (Turco) 89:4–20; *see id.* at 109:21–111:19 (explaining that, although one venture-capital fund expressed initial interest, discussions ultimately fell through).

28. At the same time, Edwards also made a separate investment in JC Medical's parent company, Genesis Medtech. 11/19 PM (Zovighian) 96:9–20; 11/21 AM (Turco) 94:16–18. Contrary to the FTC's suggestions of regulatory avoidance, this investment gave Edwards access and insight into the Chinese market. 11/19 PM (Bobo) 133:12–23; 11/19 PM (Zovighian) 98:8–18. Also, under Chinese law, Edwards cannot distribute its devices directly and currently works with hundreds of distributors; Genesis has the potential to be a sole distributor. 11/19 PM (Zovighian) 97:2–11.

29. In acquiring both JenaValve and JC Medical, Edwards did not believe that it was buying the entire TAVR-AR industry or that it had insulated itself from future competition. 11/19 AM (Wood) 84:6–11. Again, as discussed and as reflected in Edwards' ordinary-course analyses of the competitive landscape, there are numerous other companies working on TAVR-AR devices.

30. Indeed, before Edwards acquired JenaValve and JC Medical, Larry Wood—the then-head of Edwards' TAVR business—wrote to his team that the two acquisitions would "be a massive signal to the world that the leader in THV thinks AR is an enormous opportunity," other companies "will race to be number two," and "[i]t will be a competition with multiple players." DX-0114; *see* 11/19 AM (Wood) 85:15–87:18. He thus cautioned his team that, "[i]f we don't move at best speed, we will waste the first mover advantage and this all will be for nothing." DX-0114; *see* 11/19 AM (Wood) 87:19–88:17. Other current and former Edwards' executives likewise testified that they anticipate fast followers. 11/20 AM (Bierman) 111:20–23; 11/24 PM (Sharma) 140:21–141:1.

D. Trilogy and J-Valve (SOJOURN) today.

31. Following its acquisition of JC Medical, Edwards has been working to develop and obtain approval for J-Valve (now called SOJOURN). In October 2024, Edwards began a pivotal trial to obtain FDA approval for inoperable and high-risk patients. 11/20 PM (Concepcion) 17:4–6. But developing a breakthrough device is rife with uncertainties and challenges, and as discussed further below, [redacted]. 11/20 PM (Concepcion) 19:9–20:25. And at this point, the "[redacted]" for FDA approval for SOJOURN is sometime in 2029. 11/24 PM (Sirimanne) 94:24–95:5; 11/19 AM (Wood) 106:12–23.

32. For its part, despite completing its pivotal trial over two years ago, JenaValve does not have FDA approval for its Trilogy device. 11/24 PM (Sharma) 156:10–13. Rather, as discussed below, JenaValve's application is [redacted]. DX-0283 at 1; 11/19 AM (Wood) 111:14–23.

33. Unlike JenaValve, Edwards has significant experience in [redacted] 11/19 AM (Wood) 108:10–24. As JenaValve's Chairman of the Board, Jan Keltjens, testified:

"[I]f this transaction would have closed as we originally hoped for a year ago, I think we would have [FDA] approval by today." 11/24 AM (Keltjens) 122:16–18; *see* 11/19 AM (Wood) 108:5–9. Unfortunately, because of the FTC's investigation and lawsuit, the Transaction remains on pause and Trilogy remains unapproved. *See* 11/19 PM (Zovighian) 78:11–13 (agreeing that "the FTC [had] already [done] a great job [of] slowing down JenaValve").

II. The Transaction will benefit competition and patients.

A. JenaValve lacks the ability to swiftly and effectively commercialize Trilogy.

i. JenaValve has struggled to obtain FDA approval for Trilogy.

34. JenaValve completed its pivotal trial for Trilogy over two years ago. 11/20 AM (Bobo) 16:3–9. Nonetheless, over two years later, Trilogy still does not have FDA approval.

35. One known—and significant—hurdle standing in the way of Trilogy's approval is JenaValve's [redacted]. 11/18 PM (Kilcoyne) 112:14–21. This "[redacted] 11/18 PM (Kilcoyne) 108:23, 112:5–11. But as one Edwards' employee wrote: "if you wanted to screw up [redacted] study you could not have thought up any worse ways to do the[] study than [JenaValve] did with their outside test lab." DX-0119 at 2. And Trilogy had to stop and [redacted], causing a year and a half delay before JenaValve could finalize its application. 11/18 PM (Kilcoyne) 112:16–113:5.

36. On September 26, 2025, while this case was pending—and after the FTC told this Court that Trilogy's approval was "imminent," Compl. ¶ 45— the FDA sent JenaValve a deficiency letter. DX-0283 at 1. That letter identified [redacted]; thus, the FDA could not conclude with "[redacted]." *Id.*

37. Primarily, the FDA concluded that [redacted] *Id.* Thus, the FDA could [redacted] *Id.*

38. During due diligence, Edwards [redacted] 11/24 PM (Sirimanne) 70:12–19; DX-0144 at 61; DX-0119 at 3 (Edwards employee explaining that while the testing "issues probably doomed the study to failure. . . . it still doesn't prove the valves would pass if they didn't make all of these mistakes.").

39. The FDA has required JenaValve [redacted] DX-0283; *see* 11/18 PM (Kilcoyne) 117:22–25 [redacted]

40. The letter also identified [redacted]. For example, the FDA [redacted] DX-0283 at 2. [redacted]. *Id.*

41. [redacted] 11/18 PM (Kilcoyne) 119:5–6. And Larry Wood, who has decades of experience with the FDA, testified that [redacted] 11/19 AM (Wood) 115:7–17.

42. [redacted] 11/18 PM (Kilcoyne) 119:10–13, 120:12–25. As discussed below, JenaValve is losing money. Indeed, as Mr. Kilcoyne testified, [redacted] 11/18 PM (Kilcoyne) 118:23–25.

43. But even if JenaValve [redacted] 11/18 PM (Kilcoyne) 117:20–118:10. This would [redacted] 11/24 PM (Keltjens) 6:10–19 ([redacted]); 11/18 PM (Kilcoyne) 119:10–13 ([redacted]).

44. Of course, even then, [redacted] *See* 11/19 AM (Wood) 114:11–115:17. And [redacted]. 11/18 PM (Kilcoyne) 118:20–25; 11/19 AM (Wood) 114:25–115:11 (explaining that the [redacted]).

45. Although Trilogy being approved quickly is a fundamental aspect of the FTC's theory, the FTC did not call any witnesses from the FDA or introduce any evidence from the FDA. And the FTC's expert, Dr. Kesselheim, was unwilling to opine on Trilogy's likelihood of approval in light of the deficiency letter. 11/21 PM (Kesselheim) 56:9–12, 56:18–23.

ii. Even if Trilogy is approved, JenaValve faces significant limitations that will hamper commercialization.

46. Even if JenaValve receives FDA approval, JenaValve faces many limitations that would likely prevent it from successfully commercializing Trilogy or innovating.

47. *First*, JenaValve does not have the resources to produce valves at the scale required to commercialize Trilogy. JenaValve "[redacted]." 11/18 PM (Kilcoyne) 113:6–8. And the cost associated with building each valve is "astronomical." 11/20 AM (Bierman) 102:24–103:2.

48. Manufacturing Trilogy valves is a complex and resource-intensive process. It first requires JenaValve to develop suitable tissue for the valve. But JenaValve has "[redacted]" 11/18 PM (Kilcoyne) 115:4–6. Indeed, [redacted] 11/18 PM (Kilcoyne) 113:6–114:4; DX-0270 at 42 ([redacted]); *see* DX-0288 (McWilliams Rep.) ¶ 77. As Mr. Kilcoyne explained, this [redacted] 11/18 PM (Kilcoyne) 113:6–114:4. And, as Mr. Sirimanne testified, these yield rates are [redacted] 11/24 PM (Sirimanne) 76:5–19.

49. Once JenaValve has usable tissue, it then needs to make the valve. Each valve is "custom-made" and "hand-stitched," requiring "about [redacted] stitches per valve." 11/18 PM (Kilcoyne) 114:9–25. "[T]here's [redacted]," and it takes "[redacted]." *Id.* "[I]t's about a [redacted] process from" start to finish. *Id.* Unfortunately, "[y]ou don't know whether you have made a good valve until the very end. All the time, money, and effort is put into the valve before you understand whether it's a good or bad valve." *Id.* As with [redacted] its [redacted]. In the first half of 2025, [redacted] of completed Trilogy valves were usable. DX-0270 at 40.

50. Because JenaValve is "not able to meet the needs right now" of patients in clinical trials, Dr. Vahl testified that, should Trilogy "became commercially available, I [redacted]" 11/21 AM (Vahl) 36:11–16. Indeed, Dr. Vahl testified that it would be "[redacted]" for JenaValve to commercialize Trilogy and he was unaware of any situation where a "small startup" had gone "all the way through the entire commercialization process themselves." *Id.* at 37:11–22.

51. [redacted]

52. *Second*, JenaValve [redacted]. JenaValve is [redacted] 11/18 PM (Kilcoyne) 122:7–16 [redacted]; DX-0270 at 62 (JenaValve is forecasted to have n[redacted]).

53. Today, JenaValve is subsisting on interim funding provided by Edwards. 11/18 PM (Kilcoyne) 103:15–21, 104:2–8. And, without the Transaction, JenaValve [redacted] 11/24 PM (Keltjens) 16:5–11.

54. *Third,* JenaValve's ability to reach patients has been severely hamstrung by its personnel limitations, including insufficient field specialists and sales and marketing employees. 11/21 AM (Pinto) 13:14–14:11; *see also* 11/20 PM (Pinto) 151:11–151:23 ("[W]e just don't have enough people to get the devices where they need to go and the people to support the cases."). Because of these limitations, JenaValve can only support roughly 20 Trilogy procedures per month. 11/20 PM (Pinto) 147:7–23. This means that JenaValve is only able to provide Trilogy to approximately 30 hospitals today, far fewer than the more than 800 sites that are capable of TAVR-AR implantations. *Id.* at 150:24–151:10.

55. As Dr. Chetcuti testified, JenaValve does not have the resources to support a national commercial launch and has had to delay clinical trials due to JenaValve's field-team limitations. 11/25 AM (Chetcuti) 11:22–12:13. Nor does JenaValve have the resources to hire the

clinical-support staff necessary for a full commercial launch. DX-0289 (Bailey Rep.) ¶ 42 n.95 (quoting JenaValve's Chief Commercial Officer who stated he was unsure whether JenaValve could ever "hire the scale of people" given that him "hiring 100 sales reps . . . [was] probably not realistic").

56. Indeed, the FTC's own physician witness, Dr. James McCabe of Beth Israel Hospital, similarly expressed concerns that JenaValve alone "does not have the infrastructure to bring the valve to the commercial marketplace on a national level." McCabe Dep. 94:18–20. He further noted JenaValve's "trouble with upscaling [its] production," which had caused "some backlog of patients." *Id.* at 94:21–95:3; *see also* Kereiakes Dep. 75:19–76:18 (patients could not access Trilogy because of supply issues).

57. JenaValve's [redacted]. 11/18 PM (Kilcoyne) 115:7–14 (testifying that [redacted]); 11/21 AM (Pinto) 13:5–8 (testifying that JenaValve "can't manufacture at scale and [JenaValve] can't get the people there to train the sites").

58. Leading structural-heart physicians testified that they [redacted] 11/21 AM (Vahl) 34:19–22. Dr. Vahl testified that he has had to tell patients [redacted] *Id.* 33:12–33:23. Dr. Chetcuti, a Principal Investigator for JenaValve's ALIGN-AR and ARTIST trials, testified that "in the past, even during studies . . . we've had to delay implanting [Trilogy] because of manufacturing issues or supply chain issues." 11/25 AM (Chetcuti) 14:9–11; *see* Kereiakes Dep. 76:3–4 ("[JenaValve] had a hiatus where we couldn't get a valve"); 11/21 PM (Pinto) 149:11–150:1.

59. Accordingly, physicians [redacted]. 11/21 AM (Vahl) 37:1–10 ([redacted]"). As Dr. Thourani testified, he has "personally witnessed . . . patients come to harm" because they could not get key support and equipment from JenaValve. Thourani Dep. 128:18–129:5.

60. On its own, JenaValve lacks the resources or experience to solve these issues. As JenaValve's Chief Medical Officer, Duane Pinto, testified: "We don't have enough people. We don't have enough valves. We don't have enough to get all the stuff done that we need to do." 11/20 PM (Pinto) 149:24–150:1; *see* 11/24 AM (Keltjens) 125:24–126:2 (testifying that, as a standalone company, JenaValve cannot meet the demand for its valves in either Europe or the US). Likewise, with its current resources, JenaValve will likely be unable to scale its production to meet future US commercial demand should Trilogy ever get approved. DX-0189 at 9 (JenaValve's 2026 production plan would require various improvements that were "not achievable" with current funding).

61. Indeed, JenaValve's own internal projections contemplate a constrained launch of Trilogy at a limited number of sites if the Transaction does not go through. DX-0189 at 11 (2025 budget lacked sufficient funding for a "[c]omprehensive buildout of internal commercial infrastructure (customer service, contracting, etc.)"); *see* DX-0288 (McWilliams Rep.) ¶ 72 (noting similar limitations). [redacted] *See* 11/25 AM (Bailey) 142:4–143:1, 145:23–146:8. Simply, as Dr. Thourani testified: "I do not think . . . that [JenaValve] will be able to go to even a hundred [TAVR] sites. Forget the 850 [sites]." Thourani Dep. 118:4–7. In turn, a constrained launch will result in fewer

patients being treated and likely more deaths. DX-0060 at 18 ([redacted]); *see* 11/18 PM (Kilcoyne) 129:17–20.

62. The Court need not guess about what would happen to Trilogy in the US if JenaValve remains a standalone company—it can look to what has happened in Europe.

63. Despite receiving European regulatory approval in 2021, [redacted] *See* 11/19 AM (Kilcoyne) 13:23–25; 11/24 AM (Keltjens) 125:24–126:2; DX-0289 ¶¶ 31–33. Indeed, JenaValve sells [redacted] valves per month. DX-0270 at 12.

64. For example, in the first two years following approval, Trilogy generated only [redacted] in revenue. DX-0046 at 10. As Dr. Bailey concluded, "[redacted]" 11/25 AM (Bailey) 143:6–7, even as [redacted] *Id.* at 145:11–13.

65. As Dr. Vahl testified: "[redacted]." 11/21 AM (Vahl) 35:21–36:2.

iii. JenaValve's limitations will likewise constrain innovation for Trilogy.

66. Even if JenaValve receives approval and commercializes Trilogy, it will lack the resources and experience to innovate.

67. Already, JenaValve has been [redacted] 11/18 PM (Kilcoyne) 123:10–15.

68. Likewise, JenaValve has been unable to implement important improvements to Trilogy that have been requested by physicians. *See* 11/25 AM (Chetcuti) 17:7–20. As Dr. Thourani explained, physicians have been requesting modifications "for eight years now" and "[z]ero" of their requests have been met because, as "a startup company," JenaValve "has not had the capability to make [the requested] changes." Thourani Dep. 119:11–120:1. JenaValve's inability to make the requested changes is likely to harm patients: "the only realistic way to treat patients with aortic regurgitation is for these [requested] device iterations to be made." *Id.* at 120:1–3.

69. Because JenaValve is "consumed with surviving" and "getting FDA approval[,]" it has not done any work to develop subsequent generations of Trilogy. 11/20 PM (Pinto) 151:24–152:10.

70. JenaValve also lacks the capabilities, including engineers, to develop a larger valve size and has repeatedly delayed investments in its large-valve program. 11/18 PM (Kilcoyne) 123:16–124:8; 11/20 PM (Pinto) 152:14–15 (JenaValve lacks funding to develop a larger valve size); *id.* at 93:3–7 (developing larger valve sizes with the limited number of engineers currently on JenaValve's staff would take two years to complete); Thourani Dep. 124:10–11 ("[JenaValve] just don't have the resources to be able to do it.").

iv. A failed first-in-kind launch can harm competition and patients long-term.

71. As discussed, without Edwards' assistance, any commercial launch will be anemic at best. This result is not only bad for patients who will not be able to receive treatment from Trilogy, but it is bad for the TAVR-AR industry. As Mr. Wood testified, even with a "great device," "if you don't train your doctors on how to use it properly and they make mistakes or they have problems because they're not properly educated, you can kill a market before it even gets started." 11/19 AM (Wood) 102:24–103:4. Likewise, Dr. Thourani testified that, without the Transaction,

physicians will only be able to "treat a miniscule amount of patients" and it will "take the field backwards," "hurt[ing] patients" in the process. Thourani Dep. 123:16–124:1.

72. [redacted]. *See* 11/18 PM (Kilcoyne) 115:19–116:3 ([redacted]). One physician described JenaValve's pivotal trial as a "s**t show." Thourani Dep. 110:3–4; *see id.* at 109:18–19 (complaining that he had to "put patients off because [JenaValve didn't] have the resources" to provide necessary support for TAVR-AR procedures).

73. The FTC's own physician witnesses testified accordingly. For example, Dr. McCabe expressed "substantial frustration" about "how long it's taken [Trilogy] to get to commercialization." McCabe Dep. 112:11–113:11. [redacted], Dr. Kereiakes [redacted] DX-0037 at 3.

74. A weak commercial launch from JenaValve would likely cement these negative impressions about JenaValve and the entire TAVR-AR space. As Defendants' industry expert, Mr. McWilliams, explained based on his 30 years of experience in the life-science innovation space, a weak launch would likely "reinforce" the "existing view" that TAVR-AR "is a small, niche market." 11/25 AM (McWilliams) 103:8–20; DX-0288 (McWilliams Rep.) ¶¶ 106, 108. This, in turn, could discourage other companies from entering the TAVR-AR space at all. 11/25 AM (McWilliams) 103:21–23 ("[N]o incentive for these other companies to want to jump into the [TAVR-AR] space.").

75. Thus, even if JenaValve manages to obtain approval and launches Trilogy, the nature of that launch could damage the TAVR-AR space, hampering competition and harming patients.

B. The Transaction will maximize the chances of successfully commercializing Trilogy.

i. Trilogy & TAVR-AR are a top priority for Edwards.

76. As Edwards' CEO testified, pioneering TAVR-AR is a "top priority." 11/19 PM (Zovighian) 95:18–20. And as the CEO conveyed to his Board of Directors, Edwards plans to "fully fund" TAVR-AR efforts and is willing to pull resources from other projects to ensure that happens. *Id.* at 99:22–100:1 (discussing DX-0156 at 10).

77. For 2026 alone, Edwards has allocated $100 million in support of Trilogy and is prepared to provide additional funding if needed. 11/19 PM (Zovighian) 103:2–17; 11/19 PM (Bobo) 61:2–9.

78. Edwards has devoted more than [redacted] full-time R&D employees to TAVR-AR development, and TAVR-AR is the [redacted] R&D budget across the company. 11/24 PM (Sirimanne) 64:3–6, 64:21–24, 66:8–12. Indeed, TAVR-AR is Edwards' fastest growing R&D project, with strategic plans estimating an annual increase in AR spend from 2025 to 2031. 11/20 AM (Bobo) 14:11–23; DX-0251 at 13.

ii. Edwards can help Trilogy obtain FDA approval.

79. As discussed, JenaValve has struggled to successfully [redacted] In several ways, Edwards could help JenaValve overcome these struggles.

80. *First*, Edwards has "been doing AWT testing from the earliest days of [its] development as a surgical valve company." 11/19 AM (Wood) 108:14–16; *see* 11/24 PM (Sirimanne) 74:5–74:6 (45 years of experience). And it has [redacted]

[redacted]. 11/19 AM (Wood) 108:16–18. As the TAVR pioneer, Edwards has [redacted] 11/24 PM (Sirimanne) 73:24–74:9, 75:1–12. Through the Transaction, Edwards could bring those resources and decades of experience to bear in helping Trilogy obtain FDA approval.

81. *Second*, Edwards could conduct Trilogy's AWT in-house. JenaValve has been relying on a [redacted] By contrast, Edwards has [redacted] dedicated to in-house valve testing. 11/19 PM (Zovighian) 80:22–81:8; *see* 11/19 AM (Wood) 115:18–116:2 (testifying that Edwards does AWT "all the time" for "every one of our valves that we commercially manufacture"). This in-house testing is superior and has "huge" benefits that "speed[] up innovation" by leveraging institutional experience and facilitating learnings between the testing and R&D teams. 11/24 PM (Sirimanne) 51:20–52:19. Simply, as Mr. Keltjens testified: "[Edwards] has a department, oodles of people, their own machines, that do [AWT testing] for a living." 11/24 AM (Keltjens) 123:3–6.

82. Edwards has the resources and experience to [redacted] just as it successfully completed AWT testing in-house on SAPIEN after acquiring PVT. 11/19 AM (Wood) 116:25–117:3. Before the FTC's lawsuit put the Transaction on hold, that was the plan. DX-0144 at 61 ("[redacted]"); 11/24 PM (Sirimanne) 73:24–74:20.

83. *Third*, if it turns out that Trilogy [redacted] because of a problem with the valve itself—[redacted]—Edwards can help

with that, too. In fact, [redacted] 11/24 PM (Sirimanne) 74:23–25. [redacted] *Id.* at 70:12–19 (discussing DX-0119 at 2–3). [redacted] *Id.* at 73:24–74:9, 75:1–12. [redacted] *Id.* at 75:19–76:4. For example, Edwards previously used its expertise in cobalt chromium and nickel titanium fabrication, testing, and performance as an "advantage[]" in developing of stronger, more durable, and longer-lasting heart valves in the SAPIEN program—issues similar to those facing Trilogy. *Id.* at 53:1–8; *see also* Thourani Dep. 126:5–127:2, 127:4–12 (explaining that Edwards' "engineering feats" in improving SAPIEN have dramatically enhanced the device's safety and efficacy and decreased the overall complication rate from 20% to less than 1%).

84. Overall, Edwards has enormous resources and experience that it can bring to bear to help Trilogy achieve regulatory approval. As JenaValve's Chairman testified, "if this transaction would have closed as we originally hoped for a year ago, I think we would have [FDA] approval by today." 11/24 AM (Keltjens) 122:16–18.

85. The FTC has suggested that the recent pause in Edwards' JOURNEY trial somehow undermines Edwards' ability to help JenaValve. Reply 17. In fact, it shows the opposite: Edwards has devoted enormous resources and expertise to fix issues likely caused by design and manufacturing choices implemented by a startup that lacked Edwards' experience.

86. Since initiating the JOURNEY trial, Edwards has twice opted to pause the study to address issues that could affect patient safety. 11/20 AM (Bobo) 44:4–6.

87. [redacted]

88. [redacted]

89. [redacted]

[redacted] And Edwards ultimately spent [redacted] million more than budgeted to conduct the investigation. 11/20 AM (Bobo) 46:3–16.

90. [redacted]

91. [redacted]

92. Edwards' recent experience with JOURNEY thus emphasizes the inherent uncertainty in the TAVR space and the resources, creativity, and expertise that Edwards brings to resolve unforeseen issues. Thus, far from suggesting that Edwards will be unable to assist JenaValve, it suggests the exact opposite.

iii. Edwards can more successfully commercialize Trilogy and the TAVR-AR space.

93. *First*, as discussed above, JenaValve has persistent manufacturing and yield issues that prevent it from meeting demand even for clinical trials and that pose an enormous barrier to the even higher demand JenaValve would face if Trilogy was approved commercially. Edwards can help resolve these issues.

[redacted]

94. [redacted]

95. Edwards has "manufactured . . . more [TAVR valves] than any other TAVR manufacturer in the world." 11/20 AM (Bierman) 91:5–8. It understands how to properly scale a TAVR business. *See* 11/20 AM (Bobo) 22:13–24. And it plans to bring this experience to bear on Trilogy's manufacturing. *See* 11/20 AM (Bierman) 91:16–20.

96. [redacted] 11/19 PM (Zovighian) 81:8–10. And it has "thousands of people in the [TAVR-AS] supply chain" that it can use to resolve Trilogy's supply-chain issues and tissue yields. 11/19 AM (Wood) 67:3–5. For example, because of Edwards' expertise and significant financial investment, 11/20 AM (Bobo) 22:1–8, Edwards' tissue yields are [redacted], 11/24 PM (Sirimanne) 76:20–22.

97. Edwards plans to immediately apply its best-in-class engineering and manufacturing teams to fix these issues and "bring [Trilogy] to [the] US market as soon as possible." DX-0160 at 28; DX-0127 at 5; 11/19 AM (Wood) 98:12–23 (Edwards plans to "get our operations people in there . . . people from R&D as well – to figure out, how do we make this device more manufacturable, how do we improve yields, how can we produce this thing at scale, and how can we produce it at a better cost structure?"); 11/20 AM (Bobo) 55:10–57:1 (discussing Edwards' plans for TRILOGY, including bringing manufacturing experts to JenaValve's plants in Leeds, United Kingdom, and Irvine, California, and increasing the size of the commercial team).

98. For example, Edwards used its Tissue Center for Excellence to accelerate the transfer of JC Medical's technology to the US and integrate Edwards' bovine pericardial tissues

and anti-calcification treatments into J-Valve post-acquisition. 11/24 PM (Sirimanne) 53:9–17, 83:23–85:4; PX-1239 at 4. Edwards would similarly use its tissue expertise to help resolve JenaValve's persistently poor tissue yields.

99. Edwards is experienced in resolving production issues at startup companies. For example, Edwards has commercially scaled other early-stage technologies—such as CardiAQ, Innovalve, and PVT—all of which had supply-chain constraints and scalability issues like JenaValve. 11/19 AM (Wood) 66:17–67:2; 11/20 AM (Bobo) 22:9–23:6.

100. *Second*, JenaValve has inadequate clinical field support to properly support the physicians conducting even clinical testing, to say nothing of future commercial application. 11/20 PM (Pinto) 151:11–18 ("[W]e just don't have enough people to get the devices where they need to go and the people to support the cases."). By contrast, Edwards is the gold standard in physician support and TAVR education.

101. Because TAVR procedures are complicated, clinical field support is "[c]ritical." 11/25 AM (Chetcuti) 13:18–23. These field teams are in the operation room and "an integral part of the preop planning and the procedural case." Thourani Dep. 112:18–113:10. And successful commercialization of TAVR-AR requires such support for the more than 850 TAVR centers that exist nationwide. 11/25 AM (McWilliams) 95:7–96:2.

102. Edwards has a "fully-fledged TAVR-AS nationwide field team" supporting its relationships with TAVR centers. 11/20 AM (Bobo) 53:3–9, 53:20–54:12. That team could be easily retrained to focus on TAVR-AR. *Id.* at 54:4–9; 11/21 AM (Vahl) 39:25–40:8. And Edwards already provides field support for the more than 850 TAVR centers that must be leveraged to successfully commercialize TAVR-AR. *See* 11/25 AM (McWilliams) 95:13–96:2. Indeed,

currently, an Edwards field support employee "attend[s] every TAVR implantation." 11/20 AM (Bobo) 53:3–6; *see also* 11/20 PM (Pinto) 137:15–138:10, 150:7–15.

103. Edwards also has the resources and experience to train and build out multiple field support teams for transcatheter heart products simultaneously, as it did with its mitral and tricuspid valve clinical programs (on top of TAVR-AS). 11/21 AM (Vahl) 39:13–23.

104. Edwards' TAVR training resources for physicians are similarly impressive. For TAVR-AS, Edwards trained every site seeking to perform procedures "by develop[ing] full simulators that could simulate the implantation of a transcatheter heart valve" for physicians to train on the procedure. 11/19 AM (Wood) 63:20–64:12.

105. Edwards also invests significant patient activation resources. It spent [redacted] on patient activation in TAVR alone in 2023, and anticipates that number nearly [redacted] by 2030. DX-0137 at 98. And Edwards plans to train its entire TAVR-AS nationwide team on the TAVR-AR devices. 11/20 AM (Bobo) 53:24–54:12; *id.* at 52:3–6.

106. Edwards could thus use its existing (and superior) TAVR field-support teams, relationships with TAVR centers, and TAVR training materials to commercialize Trilogy faster and more robustly than JenaValve could alone.

107. *Third*, more broadly, both JenaValve and leading physicians agree that Edwards will be able to commercialize and scale Trilogy in a way that a standalone JenaValve cannot.

108. JenaValve's leadership anticipates that Edwards will be able to treat many more patients than an independent JenaValve. *See* 11/18 PM (Kilcoyne) 75:2–11 (discussing PX0031 at 19). As Defendants' economic expert Dr. Bailey testified, physicians have pointed to JenaValve's lack of resources as part of their "real world experience" and "the impact to them and the impact to their patients." 11/25 AM (Bailey) 148:5–7. And Edwards has the resources that JenaValve lacks.

Id. at 148:12–149:1. Absent Edwards' capabilities and only relying on JenaValve's limited resources, many of these patients would [redacted] 11/21 AM (Vahl) 35:2–5.

109. Edwards' and JenaValve's confidence in Edwards' ability to manufacture and sell Trilogy at scale is backed by the medical community. In sharp contrast to shortages physicians have experienced with JenaValve, Dr. Thourani testified that, in his "19 years of doing Edwards valves," Edwards has never turned him away. Thourani Dep. 130:12–131:1. Dr. Thourani further noted that Edwards is the only company that has the engineers, money, and track record to invest in developing improved versions of the Trilogy valve. *Id.* at 119:5–120:7.

110. [redacted] 11/21 AM (Vahl) 38:20–39:12.

111. As to field support, Dr. Vahl was confident Edwards would have sufficient coverage for all TAVR-AR needs as well as its other structural heart programs given Edwards' "strong track record" of "building out . . . clinical specialist team[s]" and experience running "multiple programs . . . simultaneously." 11/21 AM (Vahl) 39:13–24. Edwards also has a "strong track record of driving research devices . . . into clinical approval and then translating clinical approval into quick availability of those devices." *Id.* at 40:9–41:8.

112. Dr. Chetcuti agreed that Edwards was the remedy to JenaValve's "scalability" ailments, testifying that Edwards' impact on AR patients would be "multi-fold" with (1) "a bigger field team that could allow more sites to be launched at a faster pace," (2) "scale of manufacturing to have more devices available," and (3) "a big company like Edwards" would encourage "further

iterative changes in the device itself to make it more deliverable and more favorable for use in the public." 11/25 AM (Chetcuti) 16:4–17.

113. The FTC's physician witnesses were in agreement that Edwards, not JenaValve, would be able to scale up production and commercialize at scale. *See* Kereiakes Dep. 81:21–82:17 (affirming that Edwards has the "resources and capabilities needed to support a national launch and roll-out of the Trilogy Valve," including the "sales force, clinical force, and production capacities" as well as "high-quality engineers" who are "very experienced in this space"); McCabe Dep. 103:10–104:13 (estimating that the ratio of the Edwards to JenaValve field team is "close to probably 1,000 to 1 . . . [I]t's probably a thousand-plus to one.").

114. The FTC's industry expert, Dr. Kesselheim, likewise agreed that large medical-device companies like Edwards provide important financial resources, as well as engineering, manufacturing, clinical, and sales support to smaller innovators (like JenaValve). These resources help organize clinical trials, negotiate the FDA process, and "manufacture devices at scale" for public deployment. 11/21 PM (Kesselheim) 81:1–19; *id.* at 81:24–82:8; *id.* at 82:9–13 (agreeing that the acquisition of a medical-device startup by a large strategic player is a normal step in the development of medical devices).

115. *Fourth*, even if JenaValve receives FDA approval to offer Trilogy commercially, the FDA requires the device developer to continue conducting post-approval studies to continuously assess the product's safety. 11/25 AM (McWilliams) 81:14–82:18; DX-0288 (McWilliams Rep.) ¶ 38. Indeed, the data required for commercial approval is the bare minimum, and additional data will likely be required in this space to convince physicians to use a breakthrough TAVR device rather than "tried and true" surgical valve replacement. 11/20 PM (Pinto) 142:2–6; *see* 11/24 PM (Sharma) 120:14–23 (testifying that, post-commercialization,

generating "clinical evidence" and "data" is needed to build the market); *id.* at 124:13–21 (because "surgery was a very well-established therapy," Edwards had to use additional clinical trials "to demonstrate that TAVR could be at least as good as surgery"). And additional clinical tests will be required over time to expand Trilogy's indications and make it more available to more patients. *Id.* at 123:25–125:5 (discussing DX-0220 at 6); DX-0288 (McWilliams Rep.) ¶ 38.

116. But, as discussed and detailed in the FDA's deficiency letter, [redacted] By contrast, in TAVR-AS, Edwards has conducted numerous clinical trials involving over 10,000 patients, and has used that data to build the TAVR-AS market and expand indications to all patient populations (even asymptomatic ones). 11/24 PM (Sharma) 123:25–125:5 (discussing DX-0220 at 6).

117. Edwards can use this experience to assist in generating the future clinical data necessary to successfully commercialize and expand Trilogy.

118. Although the natural consequence of the Transaction will be increased output and more treatment for more patients, the FTC suggested that output would not increase. 11/18 AM (Pl.s' Opening) 27:9–11. In doing so, the FTC compared JenaValve's projections of future Trilogy production to certain projections in Edwards' documents. *See* 11/25 AM (McWilliams) 123:14–124:5; PDX-001 at 20. But this is an apples-to-oranges comparison: comparing a conservative valuation model prepared for Edwards' board in assessing acquisition price against an optimistic projection prepared by JenaValve to build investor interest in the company. 11/25 AM (McWilliams) 133:12–134:8. Indeed, as Mr. Bierman—Edwards VP of Strategy, who has worked on several startup acquisitions—testified, it is "typical[]" for a startup's forecasts to be unrealistically "ambitious." 11/20 AM (Bierman) 104:9–21. "They want to make sure that their company that

they're selling is going to be valued as high as possible, and one way to do that is to paint a very rosy picture on what your future sales are going to be." *Id.* at 104:15–18.

119. Notably, the FTC's economist has no opinion on this point: he did not analyze whether the Transaction will result in fewer TAVR-AR devices being produced or decrease production of Trilogy or implants in US patients. 11/24 AM (Wilson) 56:9–13, 58:20–23. In any event, this entire theory ignores JenaValve's repeated inability to meet internal targets and its history of being unable to support demand for Trilogy.

C. The Transaction will create competition by paving the way for "fast followers."

120. Being the first-to-market in the structural-heart device industry comes with "incredible challenges"—training physicians, enrolling patients, gaining confidence in the device, not to mention the various regulatory hurdles. 11/20 PM (Pinto) 138:21–139:16. Being second-to-market is much easier. Once the first mover builds "the infrastructure" needed to run a trial for a particular device, development for follow-on devices is easier. *Id.* at 139:17–140:2. Indeed, the pioneering device may even shorten the FDA approval timeline for follow-on devices. 11/21 AM (Vahl) 24:925:11.

121. Thus, so-called "fast followers"—who wait until the viability of the market is established and then quickly enter—are common in this space. 11/21 PM (Kesselheim) 82:14–22; *see id.* at 83:17–84:16 (testifying that device manufacturers made investments in the coronary stent space after Johnson & Johnson established the market opportunity); 11/25 AM (McWilliams) 101:25–102:18.

122. This was precisely what happened in TAVR-AS. After Edwards proved the market opportunity, Medtronic, Abbott, and Boston Scientific each invested in the space and entered with their own devices. 11/21 PM (Kesselheim) 84:22–85:21; 11/25 AM (Bailey) 150:4–151:7; DX-0114 at 1; DX-0289 (Bailey Rep.) ¶¶ 24–25. Indeed, when Edwards acquired PVT, multiple other

companies, including "Johnson & Johnson, Medtronic, and Boston, who were all on the board of PVT" had the opportunity to acquire PVT, but "[t]hey let Edwards buy it. They said it's too early, it's too risky." 11/19 AM (Wood) 86:20–87:10. But "once [Edwards] demonstrated that it really was a real opportunity," the other strategics began to enter. *Id.*

123. Here, multiple large US strategic developers are monitoring the TAVR-AR space and have even considered investments in TAVR-AR devices. But these strategics have thus far deferred entry due to concerns that the opportunity size does not justify the up-front investment needed to build the market. 11/18 PM (Kilcoyne) 130:1–131:5; *see also* 11/25 AM (McWilliams) 89:15–90:3 (testifying that other strategic buyers appear less interested in investing in TAVR-AR because of the unknown size of the market relative to the TAVR-AS market).

124. [redacted]

[redacted]

125. [redacted]

126. The fact that [redacted] in the year since Edwards agreed to acquire JC Medical and JenaValve can be expected, as (1) the FTC's challenge has created uncertainty and (2) Edwards has yet to demonstrate the viability of the space. *See* [redacted]

127. Considering the [redacted], and the historical experience in TAVR-AS, it is likely that, if Edwards successfully builds the TAVR-AR space, some of these companies will follow. *See* [redacted]

[redacted]). As discussed, there are numerous companies working on TAVR-AR devices that these larger companies could acquire or invest in.

128. Also, in successfully building the TAVR-AR space, Edwards will pave the way for startups to enter on their own without a larger company's help. For example, Edwards own ordinary-course competitive analyses anticipate that Jenscare—whose TAVR-AR device is already commercially available in China—will enter the US with a TAVR-AR device. 11/20 AM (Bierman) 107:8–109:20 (discussing DX-0197 at 15).

D. The Transaction will enhance TAVR-AR innovation, allowing more patients to be treated faster and with better outcomes.

i. Edwards' capabilities in R&D and TAVR are unmatched.

129. Edwards views R&D innovation as "core to transform[ing] the future of structural heart disease." DX-0291 at 29; 11/20 AM (Bobo) 10:25–11:8. Although "established companies . . . [are] generally risk averse regarding the highest risk and most innovating medical technology," 11/21 PM (Kesselheim) 83:5–9 (discussing DX-0298 at 5), Edwards' innovation strategy involves taking significant risks to reach untreated patient populations, 11/24 PM (Sirimanne) 41:24–42:3; *see id.* at 49:1–8 (Edwards invests in "breakthrough innovations . . . first-of-a-kind devices. No one has done this before").

130. Accordingly, in 2025, Edwards is expected to spend over [redacted] on R&D—or nearly [redacted] of its net revenue. 11/19 PM (Zovighian) 84:8–12. This [redacted] Edwards' competitors in the TAVR space, which average between [redacted]. *Id.* at 84:13–20; *see* DX-0022; DX-0059 at 29. As Dr. Chetcuti testified: "the way profits are rediverted into research and internally is very different in Edwards and Medtronic." 11/25 AM (Chetcuti) 39:9–11.

131. Edwards' commitment to R&D extends to pre-commercial devices. 11/19 PM (Zovighian) 87:10–20. For example, Edwards invested over $3.5 billion in TAVR-AS pre-

commercialization. 11/19 AM (Wood) 76:4–10. Likewise, Edwards invested approximately $3 billion in R&D before commercializing its mitral TAVR device (which treats a different heart valve). *Id.* at 87:10–20.

132. Edwards has invested billions into R&D for TAVR over the past two decades. *See,* DX-0220 at 4, 5, 9; 11/25 AM (Bailey) 151:11–19 (testifying to Edwards' "continual investment in [TAVR] innovation") (discussing DX-0289 (Bailey Rep.) ¶ 27, Ex. 4). That number is expected to increase, as TAVR-AR R&D is the "highest percent growth R&D project in [Edwards'] strat[egic] plan." 11/20 AM (Bobo) 14:20–15:6; DX-0251 at 11; DX-0252 at 6.

133. In addition to funding, Edwards has the "huge team of engineering talent" required "to get a product from concept to commercialization." 11/24 PM (Sirimanne) 44:10–16. Edwards has thousands of experienced R&D engineers. DX-0211 at 6 (Edwards has over 2,000 R&D engineers); *see* DX-0291 at 5 (Edwards' R&D engineers have a combined 3,538 total years of relevant experience; 30% of engineers have over 10 years of experience and 10% have over 20 years of experience). Indeed, Edwards has hundreds of R&D engineers devoted to transcatheter heart valves. 11/24 PM (Sirimanne) 44:10–23 (Edwards' transcatheter-heart-valve business unit employs 150 R&D engineers and 300 manufacturing, quality, development, and packaging engineers); *id.* at 45:10–18 (Edwards' Israeli Innovation Center (EIIC) additionally employs 150 engineers on cutting-edge R&D).

134. Edwards also operates five engineering Centers of Excellence: cross-business research centers specializing in researching metallurgy, tissue engineering, textile engineering, catheters, and packaging. 11/24 PM (Sirimanne) 47:15–25, 52:22–53:17. Edwards' tissue engineering Center for Excellence consists of PhD field experts. *Id.* at 74:10–20. Similarly, its Metals Center for Excellence houses PhD metallurgy experts "whose entire expertise is in fracture

mechanics"—[redacted]. *Id.* at 75:19–76:4. And Edwards has 45 years of "bench to clinical" experience generating physiological models to evaluate the impact of first-of-a-kind devices inside a living patient. 11/24 PM (Sirimanne) 49:19–50:11; DX-0211 at 5 ("Clinically relevant bench testing ensures *real-world* performance.").

135. Edwards' R&D team has successfully innovated six generations of SAPIEN valves in TAVR-AS. *See also* Thourani Dep. 126:5–127:2, 127:4–12 (Edwards' "engineering feats" have dramatically enhanced SAPIEN's safety and efficacy).

136. And Edwards initiated more clinical trials (and enrolled more patients) within the first five years of SAPIEN's FDA approval than any competitor did during same time period after their own TAVR-AS devices launched. DX-0298 (Bailey Rep.) ¶ 28, Ex. 5 (Edwards conducted 8 clinical trials compared to Medtronic (6), Boston Scientific (2), and Abbott (2)); *id*. ¶ 27, Ex. 4. (Edwards' trials enrolled 7,376 patients compared to Medtronic (3,906), Boston Scientific (2,330), and Abbott (1,520)).

137. No other company has the commitment, resources, or experience in R&D that Edwards provides, which is critical for developing a breakthrough device like TAVR-AR. 11/20 AM (Bobo) 56:4–57:1.

ii. By combining complementary R&D streams, Edwards can innovate faster and treat more patients.

138. "Aortic regurgitation is a complex disease." 11/24 PM (Sharma) 139:9. Each patient's physiology is unique. *See id.* at 139:9–10. AR patients may have different sized, shaped, and positioned hearts and a different number or shape of valve leaflets. *See id.* at 139:10–13; 11/20 PM (Concepcion) 35:12–22. Similarly, some AR patients have no stenosis (*i.e.*, "pure AR") whereas others have a mixed form of the disease. 11/19 AM (Wood) 77:16–20. In short, "[p]atients have different anatomy and different disease." 11/19 PM (Zovighian) 94:18–19.

139. This has two practical consequences for device development. First, because patient anatomies and disease presentation are heterogenous, a homogenous device design may not be equally effective (or even an option) for all patients. 11/20 PM (Concepcion) 35:12–22; 11/21 PM (Zovighian) 94:18–24. Second, and also because the space is still in nascency, the optimal design (or designs) for a TAVR-AR therapy is not yet known, and the tradeoffs between different design choices are uncertain. 11/20 AM (Bobo) 36:8–37:18.

140. Due to this complexity and uncertainty, in Edwards' experience, physicians and patients need a diverse and comprehensive "toolbox" of therapies. 11/24 PM (Sirimanne) 47:6–14; 11/20 AM (Bobo) 34:20–24 ("[E]very one of our leading platforms . . . ha[s] DNA from multiple developments, multiple technologies, and in many cases multiple acquisitions of early-stage technology."). Edwards expects the combination of Trilogy and SOJOURN with Edwards' internal technologies will create a toolbox for treating AR. 11/24 PM (Sharma) 139:7–16; DX-0288 (McWilliams Rep.) ¶ 118; *see also* DX-0220 at 23.

141. *First*, SOJOURN and Trilogy are "complementary technologies." 11/24 PM (Sharma) 139:15–16 (discussing DX-0220 at 22). [redacted]

142. Accordingly, SOJOURN's lower profile and smaller size make it particularly well-suited to address patient anatomies that Trilogy cannot treat, such as patients with larger annuli or certain anatomical variations in aorta positioning. 11/19 AM (Wood) 83:13–17; DX-0078 at 1–2; DX-0160 at 26. Conversely, Trilogy's design may [redacted]. 11/24 PM (Sirimanne)

96:1–8; 96:17–97:3. Likewise, Trilogy's and SOJOURN's differentiated leaflet anchoring mechanisms may be better suited for different patient anatomies. 11/19 PM (Zovighian) 94:18–24; 11/21 AM (Turco) 99:16–23; 11/25 PM (Bailey) 68:1–10. And, because of the differences in designs, it is estimated that SOJOURN can treat 20–30% of AR patients that cannot be treated by Trilogy. 11/19 PM (Zovighian) 94:11–25 (discussing DX-0109 at 3). The additional patient population that SOJOURN can treat translates to a [redacted] incremental profit incentive for Edwards to continue developing SOJOURN post-Transaction. 11/25 PM (Bailey) 18:13–19:20; DX-0289 (Bailey Rep.) ¶ 81, Ex. 22.

143. Thus, as Edwards CEO Bernard Zovighian testified, Edwards needs *both* devices to be able to treat all AR patients. 11/19 PM (Zovighian) 94:18–24; *see id.* at 95:20 ("[W]e need both companies.").

144. *Second*, by combining both R&D streams and gaining access to both sets of clinical data, Edwards can accelerate innovation for both devices in a 1+1=3 scenario.

145. This is precisely what happened in TAVR-AS. By combining Edwards' internal R&D stream with PVT's R&D stream, it empowered Edwards to "massively accelerate the development" of a commercially approved TAVR-AS valve. 11/19 AM (Wood) 62:21–63:6. For example, at the time of the PVT acquisition, PVT had successfully developed a TAVR deployable valve, but lacked a delivery system. 11/24 PM (Sirimanne) 54:5–13, 54:17–55:5. Edwards had a completed delivery system, but its internal valve program was at least four years from a first-in-human study. *Id.* at 54:6–9. By combining Edwards' delivery system with PVT's valve, Edwards was able to accelerate SAPIEN's commercialization. *Id.* at 54:5–13, 54:17–55:5; 11/19 AM 63:3–10 (Wood).

146. So too here, Edwards expects that combining the R&D streams for SOJOURN and Trilogy will enable improvements to both device platforms and accelerate innovation for future generations. PX1253 at 82–84; 11/24 PM (Sirimanne) 97:20–98:9 ("[F]rom an engineering perspective, if you have access to the clinical data and we have two systems which we think might be suitable for different patient population[s] . . . we can learn so fast with access to both systems and improve on that."); 11/19 PM (Zovighian) 105:22–106:3; 11/20 AM (Bobo) 32:2–13; DX-0160 at 26–30.

147. Importantly, this will give Edwards access to the clinical data and learnings of each device, as JenaValve's data is currently unavailable to Edwards. Indeed, even failures and setbacks in an R&D stream lead to future product improvements. 11/24 PM (Sirimanne) 47:5–14; *see id.* at 50:12–22 (Edwards "learn[s] from failures to refine designs"); 11/24 PM (Sharma) 139:7–16; DX-0221 at 5; *see also* Thourani Dep. 121:16–122:1. Edwards is a "very data driven company" that goes "where the data takes us." 11/24 PM (Sharma) 122:14–23. This data is key to driving innovation. *Id.* at 122:19–23 ("[U]nderstanding the evidence from clinical trials as well as our customer experience in the market as we scale is really important to inform where the portfolio should go and where we should make sure that we make improvements.").

148. For this reason, the FTC's attempts to discount Edwards' innovation capabilities due to a supposed lack of "integration planning," 11/18 AM (Pl.'s Opening) 34:14–35:1, fall flat. For example, as discussed, Edwards has repeatedly innovated its SAPIEN device, yielding massive benefits to patients. *See* 11/24 PM (Sharma) 122:3–13 (discussing DX-0220 at 6). As Ms. Sharma testified, it would have been nearly impossible for Edwards to have planned these generations in advance precisely because Edwards follows the data. *Id.* at 122:14–23. For example, the data revealed that patients who had "a lot of bleeding in their access site at the femoral artery . . . died

more often." *Id.* at 123:2–7. This drove Edwards to find a way to "reduce the size of the device as it entered the femoral artery," which is "how SAPIEN XT was born." *Id.* at 123:8–10. Similarly, as Edwards expanded indications into lower-risk patients, the data showed that such patients are "oftentimes younger," meaning that the durability of the device became "particularly important." *Id.* at 123:13–24. This led to Edwards developing a new, "advanced tissue" called Ultra Resilia, which "designed to enhance long-term durability." *Id.*

149. In the TAVR space: "[t]here's no way to anticipate what the scope of a future generation device is going to be without learning from a previous generation device[]." 11/20 AM (Bierman) 97:7–9. As discussed, the evidence shows that Edwards will follow the data and bring its substantial experiences and resources to bear, innovating a TAVR-AR device in the same way that it has innovated in the TAVR-AS space.

150. Again, after receiving commercial approval for SAPIEN, Edwards proceeded to refine the tools in its toolbox through subsequently developing six further SAPIEN generations, each informed by clinical trial data, post-market commercialization studies, and independent medical research, as well as close engagement with physicians. 11/24 PM (Sirimanne) 46:7–47:14; 55:23–56:4. And Edwards expects the AR "journey to be similar to [AS]." DX-0220 at 23. It will build the toolbox through generational development, in which the learnings from and challenges faced by prior devices inform successive generations, and which progressively improve outcomes for patients. *See* 11/24 PM (Sirimanne) 62:24–63:1, 77:21–79:10 (discussing PX-1253 at 82–83); 11/24 PM (Sharma) 140:1–20 (discussing DX-0220 at 23); 11/25 AM (Chetcuti) 17:21–18:6.

151. By contrast, as discussed, JenaValve has no plan to develop any next-generation Trilogy system, nor a realistic pathway to make improvements to the existing device that would

allow for next-generation planning discussions. 11/20 PM (Pinto) 151:24–152:10; 11/21 AM (Pinto) 13:14–14:4.

152. Thus, the Transaction will benefit competition and patients, not just now, but also for years to come through enhanced innovation.

E. The FTC's speculated alternatives to the Transaction are unsupported by the evidence.

153. *First*, despite JenaValve's dire financial condition, the FTC suggests that it does not need the Transaction because it could just raise more money, including through an Initial Public Offering ("IPO"). 11/18 PM (Kilcoyne) 67:23–68:9; 11/18 AM (Pl.'s Opening) 40:7–23. This is unsupported by the evidence.

154. Obtaining FDA approval ([redacted]), resolving manufacturing and scalability issues, and building the TAVR-AR space will all require significant funds. For example, JenaValve estimates it will need s[redacted] to meet its forecasted production and investment goals. DX-0288 (McWilliams Rep.) ¶ 88 (citing DX-0270 at 56). JenaValve's own projections indicate that a successful commercial launch would require significant additional financial investment and time, including quadrupling its professional education and training force, adding 30 employees to educate and train physicians on the use of Trilogy, and providing coverage for procedures at all commercial and clinical sites. *Id.* ¶ 69.

155. [redacted] 11/18 PM (Kilcoyne) 122:4–10 ([redacted]); *id.* at 122:17–20 ([redacted]); 11/24 PM (Keltjens) 19:7–19 ([redacted]).

156. Today, JenaValve is relying on interim funding from Edwards. 11/18 PM (Kilcoyne) 119:16–22. [redacted] 11/24 PM (Keltjens) 4:19–5:7–14; 11/18 PM (Kilcoyne) 120:1–5.

157. JenaValve estimates that it would need to raise approximately [redacted], and a total of between [redacted] neither of which are readily available prospects. 11/18 PM (Kilcoyne) 120:12–25, 126:1–17; 11/24 PM (Keltjens) 5:10–14.

158. JenaValve's ability to raise private capital as a standalone company is limited. [redacted] 11/24 PM (Keltjens) 21:7–22. Without the Transaction, investors are likely to be reluctant to offer JenaValve additional funding. 11/25 AM (McWilliams) 90:4–91:14. [redacted] 11/24 PM (Keltjens) 12:9–11.

159. As for an IPO, JenaValve's Chairman believes it is "impossible" for a pre-revenue company with a limited cash runway and significant uncertainty about when and how to get PMA approval for its product to successfully complete an IPO. 11/24 PM (Keltjens) 16:24–17:3. Defendants' industry expert testified to the same: "I don't feel like there's any way [JenaValve] can do an IPO today . . . . [because] in medical devices, the bar has consistently been, you need to be generating revenue of $50 million or more annually, high growth rate, with good gross margins." 11/25 AM (McWilliams) 91:15–92:1. Without the Transaction, JenaValve itself will be in jeopardy and will be in no position to successfully commercialize Trilogy.

160. Even in the very best-case scenario, JenaValve's forecasted income from an IPO would likely be [redacted]. DX-0288 (McWilliams Rep.) ¶¶ 88–89. [redacted] 11/24 PM (Keltjens) 19:7–19:19.

161. *Second*, the FTC argues that JenaValve does not need *this* Transaction, because it could be purchased by some other company. But there is no evidence to conclude that some other company is going to save JenaValve. To the contrary, the evidence showed, as JenaValve's counsel explained: "There's no white knight." 11/18 AM (JenaValve's Opening) 79:24.

162. As discussed, although other companies have been monitoring the TAVR-AR space, only Edwards was willing take the risk and acquire JenaValve. As to the TAVR-AR opportunity, right now: "[redacted]" 11/24 PM (Keltjens) 22:9–11. But "[redacted]." *Id* at 22:11–12.

163. [redacted] 11/18 PM (Kilcoyne) 131:17–22; 11/24 PM (Keltjens) 9:2–20; *see* DX-0074 at 17. As Mr. Keltjens testified: "[redacted]." 11/24 PM (Keltjens) 8:17–20.

164. The FTC claimed that [redacted] had offered to acquire JenaValve. 11/18 AM (Pl.'s Opening) 40:8–12. [redacted] 11/18 PM (Kilcoyne) 96:15–97:8; 11/24 PM (Keltjens) 24:18–25.

165. [redacted] 11/24 PM (Keltjens) 10:12–21, 16:5–11 ([redacted]).

166. The FTC offered no evidence showing that any other company—much less a company with Edwards' experience and capabilities in the TAVR space—has any material interest in acquiring JenaValve in the foreseeable future. And without such an acquisition, the evidence shows that JenaValve will likely be unable to successfully commercialize Trilogy and certainly will not be able to commercialize Trilogy with the success it would have if the Transaction goes through.

III. The FTC has failed to establish a valid relevant market.

A. The FTC's proposed market is gerrymandered to find harm.

167. Although the FTC alleges three different theories of harm, it alleges just one market: TAVR-AR devices in the United States. Compl. ¶¶ 35, 40. For reasons discussed below, the FTC's failure to match its theories to a viable relevant market is fatal. But even on its own terms, the FTC's market fails. Through various modifications, it whittled down its proposed market until only Edwards and JenaValve were left, leaving the FTC with its sought "two-to-one merger-to-monopoly." 11/18 AM (Pl.'s Opening) 14:20. But the evidence does not support such gerrymandering, which excludes reasonably interchangeable products and recognized competitors.

168. To begin, the FTC's market excludes surgical aortic valve replacement ("SAVR"). But SAVR is the prevailing treatment for AR patients. As both Dr. Pinto and Ms. Sharma explained, TAVR trials are compared against SAVR because it is the "tried and true" method of treatment. 11/20 PM (Pinto) 141:4–142:6; *see* 11/24 PM (Sharma) 124:13–21. Indeed, definitionally, intermediate- and low-risk patients face fewer complications from surgery. *See* 11/24 PM (Sharma) 133:6–12; *see* 11/20 PM (Pinto) 144:6–11 (noting that such patients "have options"). In all

likelihood, SAVR will remain the best option for such patients for years to come. For example, it took Edwards 5 years to expand its TAVR-AS device into these patient populations. 11/24 PM (Sharma) at 133:16–21. And ARTIST, which seeks to make Trilogy available for these patient populations will not be complete for many years. *See* 11/18 PM (Kilcoyne) 136:20–137:6 (explaining that JenaValve's ARTIST trial for intermediate and low risk patients will take 18 months to enroll and is a ten-year study).

169. Simply, TAVR competes with SAVR, particularly for low-risk and intermediate-risk patients, 11/24 PM (Sharma) 125:2–5, which make up a majority of the FTC's market, which is not limited to any particular risk population. Of the ~100,000 Americans with severe symptomatic AR that are potential candidates for a TAVR treatment, ~40,000–60,000 are intermediate or low risk and thus "likely to receive surgical treatment." DX-0160 at 24. By contrast, only ~16,000–24,000 are inoperable or at high risk for surgery. *Id.* The FTC's economist excluded SAVR from his relevant market, 11/24 AM (Wilson) 24:9–20, without performing any quantitative analysis of the relevant market or consumer demand, *id.* at 69:1–14. In doing so, he ignored the fact that 40–60% of the patients at the core of the FTC's market are good candidates for SAVR and will likely be using SAVR either exclusively or predominantly for many years to come. This mismatch alone defeats both the FTC's relevant market and the shares Dr. Wilson attempted to calculate.

170. The FTC also excludes TAVR-AR devices not currently in pivotal trials in the US. *See* 11/18 AM (Pl.'s Opening) 24:25–25:19. This eliminates the many companies working on TAVR-AR devices around the world: Laguna Tech, Shanghai Kindly, Jenscare, KOKA Lifesciences, Microport, Cusper, Healing Medical, Venus MedTech, and NewMed. 11/20 PM (Pinto) 131:20–24; 11/20 AM (Bierman) 106:14–110:25 (discussing DX-0197 at 15); 11/21 AM

(Vahl) 25:12–25. Many of these companies are either in a clinical-testing phase or have already obtained commercial approval outside of the United States. 11/21 PM (Kesselheim) 63:16–25; DX-0288 (McWilliams Rep.) ¶ 128; *see* 11/20 PM (Sun) 69:10–70:10. But, from an innovation-competition perspective, Edwards considers all companies working on devices regardless of the development stage, 11/20 AM (Bierman) 111:4–12, as reflected in ordinary-course competitive analyses. DX-0228 at 7–8; DX-0197 at 15; DDX-002 at 42 (citing DX-0041 at 30, 35). For example, the FTC points to various documents as proof of competition between J-Valve and Trilogy that occurred *before* J-Valve had started its US clinical trials or received an IDE. PX-2436 at 2; PX-2061 at 4; PX-1037 at 16; 11/24 AM (Wilson) 65:8–21 (discussing PX-2181 at 2); PDX-009 at 32 (citing PX-2462 at 17); *see also* 11/21 PM (Turco) 59:16–22.

171. The FTC's market also excludes transapical TAVR-AR devices. PX-8001 (Wilson Rep.) ¶ 27 ("[W]hen I discuss TAVR-AR products, I am referring to transfemoral ones unless specifically noted."). But transapical and transfemoral devices are both transcatheter-aortic-valve-replacement devices. 11/24 PM (Sharma) 136:20–25. A valve can be delivered either transapically or transfemorally, 11/24/2025 PM (Sharma) 137:6–13, and delivery systems can be switched between the two. 11/24 PM (Sharma) 137:14–17. As explained by Dr. Turco, "[J-Valve] started as a transapical product" and was then switched to a transfemoral system. 11/21 AM (Turco) 100:13–20.

172. The FTC's market apparently excludes transcatheter valve-*repair* devices. *See* 11/18 PM (Kilcoyne) 14:3–17. But these are transcatheter devices used to treat aortic regurgitation. 11/18 PM (Kilcoyne) 14:21–24; 11/20 AM (Bierman) 109:21–110:14.

B. Dr. Wilson's "hypothetical monopolist test" was improperly conducted and does not support the FTC's proposed market.

173. Dr. Wilson purports to conduct a hypothetical monopolist test ("HMT) to support the FTC's relevant market. 11/24 AM (Wilson) 17:23–18:9, 22:22–23:17. HMTs are typically applied to commercial markets, and are conducted with sales or other data to observe "how consumers behave quantitatively." 11/25 PM (Bailey) 5:10–24. There are several flaws with this analysis.

174. *First*, Dr. Wilson conducted no quantitative or data analysis to perform his HMT. 11/25 PM (Bailey) 5:19–6:2; 11/24 AM (Wilson) 23:3–25:6. Instead, he conducted a qualitative analysis, relying on documents and testimony to "follow[] the thought exercise of the hypothetical monopolist test." 11/24 AM (Wilson) 23:4–4. But as Dr. Wilson himself has conceded outside this litigation, such qualitative analysis is less reliable than the quantitative analysis typical in an HMT. 11/25 PM (Bailey) 6:18–7:1.

175. *Second*, Dr. Wilson's HMT is contradicted by his own observations of the current state of the TAVR-AR space. 11/25 PM (Bailey) 7:5–15. A "foundational assumption" of an HMT is that the participants in the space being evaluated are profit maximizing, and Dr. Wilson makes that assumption. *Id.* Yet, no TAVR-AR device is yet commercially approved in the US. 11/25 AM (McWilliams) 100:8–16. Rather, they are in development or in clinical trials. But companies do not make commercial sales or a profit in such trials. 11/19 AM (Wood) 58:6–11. And Dr. Wilson admits in his report that, in conducting clinical trials, firms are not profit-maximizing. PX-8001 (Wilson Rep.) ¶ 116; *see* 11/25 PM (Bailey) 7:12–15. This industry reality invalidates Dr. Wilson's attempt to use an HMT to support the FTC's relevant market here. 11/25 PM (Bailey) 6:3–12.

176. At bottom, Dr. Wilson's test assumes the FTC's conclusion—that the market is limited to Edwards and JenaValve—and then offers his subjective interpretation of select documents without any reliable economic analysis.

C. The *Brown Shoe* indicia do not support the FTC's proposed market.

177. The FTC also attempts to justify its proposed market with the *Brown Shoe* practical indicia. But the FTC has not shown that these indicia adequately support its market.

178. *Industry or Public Recognition*: The FTC argues that this factor supports its market because Defendants' documents refer to TAVR-AR as a distinct product. 11/18 AM (Pl.'s Opening) 23:12–19. But those documents do not, as the FTC's market requires, exclude transapical TAVR-AR devices, valve-repair devices, or TAVR-AR devices not yet in pivotal trials. DX-0197 at 15; DX-0228 at 8–9. To the contrary, as discussed, transapical devices *are* TAVR-AR devices, and Defendants' documents identify *all* TAVR-AR devices as part of the competitive landscape, regardless of whether the device is in a pivotal trial.

179. *Peculiar Characteristics and Uses*: The FTC offered no evidence that SOJOURN and Trilogy have different characteristics or uses from the various other transfemoral TAVR-AR devices in development.

180. *Unique Production Facilities:* The FTC offered no evidence or argument regarding this factor. *See* PDX-001 at 23.

181. *Distinct Customers*: The FTC argued only that Defendants' documents "focus on people with severe, symptomatic AR." 11/18 AM (Pl.'s Opening) 23:2–3. But the FTC offered no evidence that either SAVR or other TAVR-AR devices target different customers. Indeed, today, surgical valve replacement is currently the *only* treatment available for severe symptomatic AR patients and, as discussed, likely will continue to be the best option for low- and intermediate-risk patients for many years to come.

182. *Distinct Prices*: The FTC's only evidence on this point is that, during due-diligence modeling, Edwards assumed the same sales price for both SOJOURN and Trilogy. PDX-001 at 26; *see* Mot. 17. But the evidence showed that this was only a placeholder during due diligence. 11/20 AM (Bierman) 101:10–102:15. Moreover, the FTC offered no evidence about how surgical valves are priced, how transapical TAVR-AR devices are priced, or how any of the other companies working on TAVR-AR devices (*e.g.*, Laguna Tech, Jenscare, Cuspa, Microport, etc.) are modeling the pricing for their devices. Thus, the FTC did not establish that SOJOURN and Trilogy have distinct pricing.

183. *Sensitivity to Price Changes*: The FTC offered no evidence or argument regarding this factor. *See* PDX-001 at 23. The only relevant evidence advanced by either party here is Dr. Bailey's analysis of the entry of SOJOURN into clinical trials of Trilogy; [redacted] DX-0298 (Bailey Rep.), Exs. 13–18.

184. *Specialized Vendors*: The FTC offered no evidence or argument regarding this factor. *See* PDX-001 at 23. To the contrary, the evidence showed that Edwards offers both SAVR and TAVR devices and offers devices that can be used both transapically and transfemorally. *See* 11/19 PM (Zovighian) 88:15–18; 11/20 AM (Bobo) 36:8–24; 11/24 PM (Sharma) 137:6–13.

D. The FTC has failed to establish a relevant geographic market.

185. The FTC asserts that the geographic market is limited to the US. 11/18 AM (Pl.'s Opening) 20:2–16. But as discussed below, the area of effective competition is global: Defendants' track innovation competitors globally, competitors often work on R&D abroad before coming to the US, and there is a track record of foreign companies bringing their TAVR products to the US either by acquisition or *de novo* entry.

IV. The FTC has failed to establish that the Transaction will substantially lessen competition.

186. The FTC failed to show that the Transaction will cause any harm to competition, much less substantial harm that would outweigh the Transaction's benefits to patients and competition. Indeed, the FTC's expert economist offered no attempt to quantify the magnitude or likelihood of the various theories of harm that the FTC pursues. 11/24 AM (Wilson) 68:5–13; 68:14–21 ("I advanced *no numerical* estimate of different types of harm." (emphasis added)). Nor did he perform any quantitative weighing of the Transaction's net effect on competition. *Id.* at 67:24–68:4. Here, the FTC presents three distinct theories of harm in three distinct areas, none of which warrant blocking the Transaction.

A. The FTC failed to prove that the Transaction will substantially lessen competition in a future commercial market for TAVR-AR.

i. The FTC's theory is too speculative because it relies on future regulatory approval by a third-party government agency that is uncertain.

187. The FTC claims that the Transaction will harm competition in a future commercial TAVR-AR market. *See* 11/18 AM (Pl.'s Opening) 26:16. But it is undisputed that there are no commercially approved TAVR-AR devices in the US today. And the FTC's theory of future harm is too speculative, relying on at least four assumptions that the FTC did not establish.

188. *First*, the FTC's theory assumes that Trilogy will receive approval "imminent[ly]." Compl. ¶ 45. But, as discussed, despite completing its pivotal trial over two years ago, JenaValve has not yet received FDA approval. [redacted] DX-0283. [redacted]. 11/18 PM (Kilcoyne) 119:10–13.

189. *Second*, the FTC's theory assumes that Trilogy will not only receive approval but that it will impose a meaningful competitive constraint on Edwards. But as discussed, a standalone

JenaValve lacks the ability to successfully commercialize Trilogy at scale and to build the TAVR-AR space, as its experience in Europe confirms.

190. *Third*, the FTC's theory also assumes that SOJOURN will receive FDA approval in the near future. Compl. ¶ 45. But, best-case scenario, Edwards does not expect SOJOURN to obtain FDA approval until 2029 at the earliest. 11/19 AM (Wood) 106:12–23; 11/24 PM (Sirimanne) 95:2–5; *id.* at 85:9–11 ([redacted]). Even then, SOJOURN's pathway to, and timing for, FDA approval remains inherently uncertain given the intrinsic uncertainties in the medical-technology space. *See* Castelli (Boston Scientific) Dep. 69:10–70:15; 11/21 AM (Vahl) 22:10–24:8. And the FTC's industry expert, Dr. Kesselheim, did not analyze the probability that SOJOURN will receive FDA approval and did not conduct any analysis about SOJOURN's approval likelihood. 11/21 PM (Kesselheim) 52:12–14; 53:18–23.

191. Notably, even though establishing a likelihood of FDA approval for not one, but two, devices is a critical aspect of the FTC's case, the FTC did not call any witnesses from the FDA. Nor did it introduce any evidence from the FDA.

192. Similarly, the FTC's economic expert, Dr. Wilson, did not perform any quantitative or qualitative analysis to address the likelihood that both SOJOURN and Trilogy would be approved. 11/25 AM (Bailey) 159:3–19. Given the inherent uncertainties surrounding breakthrough devices, there is a possibility that *neither* Trilogy nor SOJOURN receives commercial approval. 11/19 (Wood) AM 106:12–23, 114:25–115:11. Even using average FDA approval probabilities—which do not account for JenaValve's specific issues or the recent deficiency letter—the probability of both devices being approved *is less than 50%*. 11/25 AM (Bailey) 161:7–9.

ii. The FTC's theory also implausibly requires the Court to assume no other device will receive commercial approval for the next six to nine years.

193. As the FTC's economic expert clarified in response to the Court's question, the FTC's theory of harm requires so-called "durable" monopoly power of at least 2–5 years. 11/24 AM (Wilson) 52:14–21. As the FTC makes clear, its issue is in Edwards owning *both* a commercially approved Trilogy *and* a commercially approved SOJOURN. 11/18 AM (Pl.'s Opening) 17:4–8 ("[T]he FTC . . . [does] not have a preference for Edwards owning one company or the other. What Edwards cannot do is own both."). But as discussed above, the earliest time in which both SOJOURN and Trilogy would be approved is some time in 2029 (assuming no delays). 11/25 AM (Bailey) 140:14–141:1. Putting together that timeline and Dr. Wilson's testimony, it becomes clear that the FTC's alleged harm will manifest, if at all, no sooner than sometime between 2031 and 2034. *See also* Compl. ¶ 45 (requiring that no TAVR-AR devices other than Trilogy and SOJOURN be approved "for the foreseeable future").

194. In addition to the legal problems with such speculation, there is no basis to conclude that SOJOURN and Trilogy will be the only commercialized TAVR-AR devices in 2031–2034. 11/25 AM (Bailey) 159:3–160:6 (explaining that Dr. Wilson did no probabilistic analysis to support his assumptions).

195. As discussed, there are numerous companies working on TAVR-AR devices, large strategics are actively monitoring the TAVR-AR space, and, if Edwards successfully builds a TAVR-AR space, it will pave the way for fast followers. *See also* 11/25 PM (Bailey) 13:23–15:1.

196. Indeed, Edwards' internal documents anticipate such entry. Shortly before Defendants finalized their merger agreement, Mr. Wood warned his team that the JenaValve acquisition would be a "massive signal to the world" that "AR is an enormous opportunity," which will encourage entry by its strategic competitors. DX-0114 at 1. He likewise warned that: "[l]ast

time, [competitors] all waited on the sideline to see if THV was real, they will not make that mistake again." *Id.* TAVR-AR, instead, "will be a competition with multiple players" and, if Edwards does not "move at best speed, [Edwards] will waste [its] first mover advantage, and this will all be for nothing." *Id.*; *see also* 11/19 AM (Wood) 85:19-86:10; 11/24 PM (Sharma); 135:2-18 (discussing DX-0114 and how Edwards' success in TAVR-AS "attracted other players to the market").

197. Separately, even if Trilogy receives approval, there is no guarantee that it will remain in the market. Given the inherently uncertain nature of the space, there is a history of TAVR devices being withdrawn after commercial approval as unforeseen issues arise. 11/21 AM (Vahl) 22:22–23:4; DX-2089 (Bailey Rep.) ¶¶ 13, 15. For example, Boston Scientific's LOTUS TAVR-AS device was approved by the FDA in 2019, but it was subsequently voluntarily recalled and discontinued a year later due to the "complexity of the delivery system, manufacturing challenges, the continued need for further technical enhancements, and current market adoption rates." *Id.*

198. In all, the FTC did not prove that, by 2031–2034, SOJOURN and Trilogy will be on the market, let alone be the only commercially available products on the market.

iii. The FTC's attempt to show harm in a future commercial market via cherrypicked JC Medical documents fails.

199. The FTC tries to sidestep the impermissibly speculative nature of its theory through various cherrypicked examples of supposed competition, none of which are sufficient to support the FTC's theory.

200. The FTC relies on materials prepared by *JC Medical* to argue that future commercial competition between J-Valve and Trilogy would result in lower prices. PX-8001 ¶ 83; 11/24 AM (Wilson) 38:19–39:5; PX-1049; PX-1066. But these materials were intended to model the overall size of the TAVR-AR market in support of JC Medical's acquisition pitch, not

accurately model future competition and pricing. 11/21 AM (Turco) 112:19–113:3, 114:4–8. They were also based on many incorrect assumptions, *id.* at 75:19–76:8, which the FTC's expert never bothered to investigate. 11/24 AM (Wilson) 86:25–87:24. For example, these materials did not account for the "many other players, including other strategics, that were working on aortic regurgitation technology." 11/21 AM (Turco) 76:17–77:1; *see* 11/24 AM (Wilson) 88:22–89:5. And some of the assumptions in these materials are plainly wrong, like when JenaValve would receive FDA approval. *Compare* 11/21 AM (Turco) 75:22–76:4 (discussing PX-1049 at 10), *with* 11/18 PM (Kilcoyne) 119:10–12. As Dr. Turco explained, relying on these materials—as the FTC does—to somehow show that no other device would be commercialized until 2035 would be "very naïve." 11/21 AM (Turco) 115:11–19.

201. Moreover, because the materials modeled a price decrease *three years after* J-Valve's projected entry, they undermine the theory that competition between J-Valve and SOJOURN is the causal mechanism. And Dr. Wilson did not analyze what, if any, portion of these anticipated price drops were caused by other confounding factors, such as economies of scale reducing production costs. 11/24 AM (Wilson) 89:22–90:11. Indeed, Edwards' ordinary-course documents analyzing Trilogy's and SOJOURN's commercial prices when both are owned by Edwards *also* model the devices' prices declining by 1%, suggesting that price decreases could be caused by any number of factors besides competition. 11/24 AM (Wilson) 91:9–17; PX-8001 (Wilson Rep.) ¶ 93, n.185 (citing PX-1078 at 55).

202. Other than assessing these one-off materials from JC Medical, Dr. Wilson did not calculate a price effect (*i.e.*, an estimate of post-Transaction price increases), nor did he analyze how, if at all, the Transaction will affect future commercial prices. 11/24 AM (Wilson) 90:12–20.

B. The FTC failed to prove that the Transaction will substantially harm innovation.

i. Edwards has strong incentives to innovate regardless of competitive pressure from JenaValve.

203. The FTC argues that the Transaction will lessen Edwards' incentive to innovate because it will not face competitive innovation pressure from JenaValve. 11/18 AM (Pl.'s Opening) 29:14–18. As discussed below, this theory ignores the various other competitor innovators currently working on TAVR-AR and overstates JenaValve's competitive significance. But it faces a more fundamental problem: Edwards has plenty of incentives to innovate that have nothing to do with JenaValve.

204. *First*, Edwards' overriding innovation incentive in the TAVR space is to fight the disease, treat more patients, and grow the addressable market.

205. As Ms. Sharma testified, Edwards' "biggest competitor . . . is the disease." 11/24 PM (Sharma) 125:9. Mr. Bierman likewise testified that Edwards' "north star" driving innovation was to "get to zero percent mortality, zero percent stroke, [and] zero percent on other complications." 11/20 PM (Bierman) 93:15–23. Until that happens, "[t]here's more that can be done through innovation to ensure that patients get the best outcomes possible" and Edwards' "job isn't done." *Id.* at 93:23–25.

206. This guiding philosophy also translates into an economic incentive to "unlock[] the market," "[drive] market growth," and treat more patients, which is ultimately "good for [Edwards'] revenue." 11/24 PM (Sharma) 125:11–15. This space is highly underpenetrated. For example, even after decades of TAVR-AS devices being on the market (and decades more of surgery being an available treatment), today only approximately *13%* of patients with severe symptomatic AS receive *any treatment*. 11/24 PM (Sharma) 129:5–17 (discussing DX-0140 at 1). Thus, again, rather than primarily innovating to compete with other TAVR devices, Edwards is

primarily innovating to access and treat the roughly 87% of patients with severe symptomatic AS that receive no treatment. *See id.* at 125:9–11 ("[T]he biggest competitors for us is the disease. This is a very, very deadly disease. And there are [an] enormous number of patients who just go untreated.").

207. Thus, Edwards has consistently focused on innovating to grow the market and reach more patients. As Ms. Sharma testified, the "vast majority" of her budget as the Senior Vice President for Strategy was focused on growing the market. *Id.* at 125:16–19. Pursuing indication expansion has been the single biggest driver of growth in TAVR-AS and other markets. 11/19 AM (Wood) 73:7–19, 74:12–17; DX-0282 at 4, 18; DX-0220 at 4, 5; 11/24 PM (Sharma) 127:21–128:6; DX-0288 (McWilliams Rep.) ¶ 26 (noting that a key aspect of Edwards' success in TAVR-AS has been its ability to grow the market). And Edwards intends to bring the same approach to TAVR-AR. DX-0160 at 27 ("We expect [the AR] journey to be like AS"); 11/19 AM (Wood) 102:20–103:20; DX-0114. Simply, the "technology itself unlocks the opportunity." DX-0140; *see* 11/24 PM (Sharma) 129:18–130:5 (discussing the same).

208. *Second*, as discussed, Edwards has built its business model, corporate ethos, and public reputation around being the innovation leader in TAVR. The idea that it would abandon all of that because of the Transaction is implausible.

209. *Third*, TAVR-AS serves as a natural experiment for how Edwards will approach innovation even without commercial competition. 11/25 AM (Bailey) 150:7–14.

210. Edwards' SAPIEN device received commercial approval for inoperable AS patients in 2011 and was the first on the market. 11/24 PM (Sharma) 125:20–25. The second device—Medtronic's CoreValve—did not receive commercial approval until June 2014. *Id.* at 126:1–6; 11/19 PM (Larkin) 34:22–35:2. But in those years in which SAPIEN faced no other commercial

competition, it did not stop innovating. Instead, by 2012, Edwards had expanded its indication from inoperable to high-risk patients, thus growing the addressable patient market.11/24 PM (Sharma) 126:7–18. And by June 2014, Edwards had also developed a second generation of the device: SAPIEN XT. *Id.* Indeed, Edwards began working on SAPIEN XT in 2006—three years before Medtronic acquired CoreValve and eight years before it received commercial approval in the US. 11/24 PM (Sirimanne) 56:23–57:1; DX-0299; DX-0300 (Medtronic purchased CoreValve in 2009); *see also* 11/24 PM (Sirimanne) 57:4–20. So, by the time that any other device received commercial approval in the US, Edwards had already expanded the patient population, developed a second-generation device, and was working on a third (SAPIEN 3). 11/24 PM (Sharma) 126:7–21; 11/24 PM (Sirimanne) 59:15–22; DX-0211 at 9; DX-0220 at 6. The FTC's industry expert acknowledged that Edwards began innovating before any other US developers had competing programs. 11/21 PM (Kesselheim) 78:1–4.

211. Even after other devices received commercial approval in TAVR-AS, Edwards continued to work on innovations that no other competitor was even attempting. For example, in 2018, Edwards began a clinical trial to obtain an indication for asymptomatic AS patients. 11/24 PM (Sharma) 126:22–127:7. Ms. Sharma testified that, to her knowledge, no other company was working on such an indication. *Id.* at 127:8–11. Edwards successfully completed that trial and received FDA approval earlier this year. *Id.* at 127:12–15. Even now, it seems that no other company is working on such an indication. *Id.* at 127:16–20.

212. As Ms. Sharma explained, Edwards "very much" has an incentive to innovate regardless of what competitors are doing because it presents "the opportunity to unlock" and "grow the market," which "has a positive impact on [Edwards'] revenue." 11/24 PM (Sharma) 127:21–128:6.

ii. Post-Transaction, Edwards will continue to face competitive pressure to innovate from the many companies working on TAVR-AR devices.

213. As discussed, Edwards has strong innovation incentives to grow the addressable market and maintain Edwards' reputation as a pioneer in the structural heart space. These incentives exist regardless of competitive pressure and are verified by the AS market. But the FTC's theory of innovation harm has another flaw. The FTC's theory myopically focuses on JenaValve, ignoring the numerous other innovation competitors whose mere potential entry drives Edwards to constantly innovate.

214. As discussed, there are numerous companies working on TAVR-AR devices today. These devices are either in the clinical in-human testing phase or have already obtained commercial approval outside of the United States. DX-0288 (McWilliams Rep.) ¶ 129; DX-0289 (Bailey Rep.) ¶¶ 105–06 Exs. 27, 28; 11/20 PM (Pinto) 131:16–24, 132:13–132:15; 11/19 PM (Zovighian) 94:3–10. This places them at the same (or a more advanced) stage of clinical development than SOJOURN. 11/19 AM (Wood) 93:4–94:24; 11/20 PM (Sun) 69:10–70:17; 11/21 PM (Kesselheim) 66:24–67:2, at 63:16–25.

215. The FTC tries to dismiss these competitors because many (although not all) are being developed outside the US and none are yet in US pivotal trials. But this ignores reality.

216. *First*, Edwards' own ordinary-course analyses assess the competitive landscape for innovation globally and regardless of the stage of development. 11/19 AM (Wood) 21:19–22; 71:14–17; 91:10–91:7; *see* 11/25 PM (Bailey) 10:16–11:12. For example, a February 2025 presentation on "Competitive Landscape: TAVR – Aortic Regurgitation" tracked the clinical stages of both US and global competitors and noted that entry of Jenscare's TAVR-AR device was "anticipated" into the US. DX-0197 at 15. An April 2025 presentation noted that Jenscare had been approved in China for AR, and tracked the number of patients in clinical studies for Microport,

KOKA Lifesciences, Hanchor Valve and others. The presentation showed that Microport and Hanchor Valve have each treated more patients than J-Valve had at the time Edwards acquired it. 11/19 AM (Wood) 93:21–94:24. Numerous other competitive analyses take a similarly broad view of innovation competition. DX-0228 at 1, 7–9. As Mr. Wood testified, "anybody who has a device, no matter how early stage it is, is a potential competitor over the long run" and "any of these [devices] can be disruptive." 11/19 AM (Wood) 91:10–92:7; *see* 11/20 AM (Bierman) 111:4–23.

217. JenaValve also tracks TAVR-AR competitors globally and without regard to development stage, including Laguna Tech, Alpha Valve, Hanchor Valve, KOKA Pioneer Valve, Ken-Valve, and Cuspa. 11/20 PM (Sun) 69:10–70:10 (discussing PX-2413 at 15); DX-0041 at 35 (identifying MicroPort and Cuspa as part of the TAVR-AR competitive landscape). It does so because [redacted] 11/20 PM (Sun) 70:22–71:2.

218. Other US strategics take the same approach. [redacted]

219. *Second*, many devices that ultimately end up in the US begin outside of the US. For example, JenaValve's Trilogy device was first developed outside of the United States, with its first in-human testing taking place in Germany. DX-0289 (Bailey Rep.) ¶ 101. JenaValve also sought commercial approval in Europe before seeking US approval for Trilogy. *Id.* Likewise, SOJOURN (then known as J-Valve) was developed in China by JC Medical, a subsidiary of Singapore-based

company Genesis MedTech. 11/21 PM 97:23–98:25 (Zovighian). Following successful commercialization in China, SOJOURN then proceeded with clinical trials in the United States. 11/21 AM (Vahl) 26:1–11.

220. Devices that are first developed outside the US may be acquired by a US strategic buyer. This is, in fact, what happened with SOJOURN when Edwards purchased JC Medical. In 2017, Boston Scientific acquired Symetis, developer of the Acurate TAVR platform, which had been commercialized in Europe but had not started clinical trials in the US. DX-0288 (McWilliams Rep.) ¶ 50. In 2011, Boston Scientific also acquired Sadra Medical, which had "recently completed a series of European feasibility studies of its Lotus™ Valve System." *Id.*

221. Medical-technology investors likewise consider the market globally and consider the competitive landscape of products that are both approved and in development. DX-0288 (McWilliams Rep.) ¶¶ 123–24.

222. *Third*, many TAVR-AR developers have recently presented at the same US conferences that JC Medical and JenaValve have presented at, suggesting a strategic focus on the US market and possible entry. *See* 11/20 AM (Sun) 69:2–20; DX-0289 (Bailey Rep.) ¶ 99 (noting prior presentations). Indeed, only two months ago, Hanchor Valve and Ken-Valve presented one-year clinical results at the TCT conference in California—on the same AR panel as Edwards. 11/25 PM (Bailey) 13:2–22; DX-0289 (Bailey Rep.) ¶ 100, Ex. 26; 11/21 AM (Turco) 121:15–19; DX-0295; DX-0296.

223. Global TAVR-AR developers also present clinical trial findings in US medical journals, confirming their interest in the US market. 11/25 PM (Bailey) 12:13–13:1; *see also* 11/25 AM (Chetcuti) 21:18–23. For example, Cusper, Hanchor Valve, Pioneer Valve and Strait Access

Technologies have published findings in the last five years. 11/25 PM (Bailey) 11:20–12:12; DX-0289 (Bailey Rep.) ¶ 98, Ex. 25.

224. *Fourth,* regardless of whether any other innovation competitor actually seeks commercial approval, the long development cycle of TAVR devices and secrecy around competitors increases the competitive pressure imposed by potential ex-US entrants. 11/25 AM (Bailey) 20:5–19. Edwards must "constantly be innovating, constantly looking over [its] shoulder" because "if [it] slow[s] down, the competitor can show up, and it will be hard to catch up given how long that development cycle is." 11/19 AM (Wood) 72:5–11; *id.* at 67:11–14 ("[T]he one certainty in med-tech is you are going to be obsoleted. You have a choice: either you obsolete yourself or someone else will obsolete you."); *see* 11/25 PM (Bailey) 20:9–19. If "Edwards does not continue to innovate, it faces the risk that a new or existing competitor in the structural heart space, using a new technology from a company abroad, comes to the US and renders Edwards' devices obsolete." DX-0288 (McWilliams Rep.) ¶ 125.

iii. Edwards has no plan or incentive to shelve or slow down Trilogy.

225. *First*, the FTC argues that an email from Ms. Sharma suggesting that Edwards stop JenaValve's ARTIST trial shows that Edwards has a lessened incentive to innovate. 11/18 AM (Pl.'s Opening) 42:1–6. It does not.

226. ARTIST is an ongoing pivotal trial to obtain approval for patients with intermediate or low surgical risk. 11/24 PM (Sharma) 151:7–9. As discussed, this sort of indication expansion is a central pillar of Edwards' strategic approach to TAVR. 11/24 PM (Sharma) 132:17–20, 154:24–155:11. But, for patients at the lower end of the surgical risk spectrum, they are often "younger" with "fewer comorbidities," and surgery can be a good option for them. 11/24 PM (Sharma) 133:6–12. Thus, before expanding a TAVR device into these populations it is "important" that a company first obtain "great outcomes" for inoperable and high-risk patients and "then very methodically

and thoughtfully step down the risk spectrum." *Id.* at 133:2–5. This is the approach Edwards successfully used in TAVR-AS. DX-0220 at 6. Indeed, Edwards did not begin its trial to expand into low-risk patients until 2016—five years after it received commercial approval for inoperable patients. 11/24 PM (Sharma) 133:13–24.

227. By contrast, as discussed, JenaValve does not yet have FDA approval for even inoperable AR patients. And it has been [redacted] Accordingly, as Ms. Sharma explained, the suggestion to stop ARTIST was so that Edwards could first ensure that Trilogy was safe for intermediate- and low-risk patients. 11/24 PM (Sharma) 132:7–133:5.

228. This in no way suggests that Edwards would not seek patient indications for Trilogy if the data showed that it was safe and effective for intermediate- and low-risk patients. *Id.* at 156:4–7. At the hearing, counsel for the FTC suggested that Edwards should not worry about patient safety in the ARTIST trial because ultimately "[t]he FDA is responsible for ensuring safety." *Id.* at 150:20–22. Not so. Everything Edwards does is centered around patients, and Ms. Sharma confirmed that Edwards is responsible for ensuring that its devices are safe and effective before being implanted into a patient's heart. *Id.* at 156:18–21.

229. In any event, Edwards has funded ARTIST. Under the merger agreement's interim operating covenants JenaValve submitted three contracts relating to the ARTIST trial to Edwards on February 11, February 25, and March 17, 2025 respectively. DX-0196; DX-0201; DX-0209. These contracts would have created multi-million-dollar obligations over the course of 10 years. 11/18 PM (Kilcoyne) 56:13–19; DX-0196; DX-0201; DX-0209. Edwards approved all three on March 28, 2025. 11/18 PM (Kilcoyne) 145:7-10; DX-0217. And Edwards' brief review, which Mr.

Keltjens characterized as unsurprising, 11/24 PM (Keltjens) 37:17–24, did nothing to impede ARTIST, which is ongoing today, 11/18 PM (Kilcoyne) 145:15–19; 11/24 PM (Keltjens) 37:9–24.

230. *Second*, the FTC claims that Edwards' decision to discontinue a TAVR-AS device in Europe (CENTERA) many years ago suggests it will do the same to Trilogy. But Edwards spent 10 years developing CENTERA, a self-expanding valve platform. 11/24 PM (Sirimanne) 60:19–61:12; 11/20 AM (Bobo) 10:6–18. Edwards did not ultimately decide to discontinue the device because it was opposed to having two devices, as the FTC suggests. Rather, the CENTERA motorized delivery system was unsafe, and resolving the issue would have added an additional three to five years to completely redesign the delivery system. Therefore, Edwards opted to focus on the SAPIEN platform, which had demonstrated superior safety and efficacy in all patient populations. 11/24 PM (Sirimanne) 61:5–23; 11/20 AM (Bobo) 10:6–18; *see also* 11/21 AM (Vahl) 28:14–29:2 (explaining Edwards "develop[ed] more than one approach simultaneously" by developing SAPIEN 3 and CENTERA at the same time but decided to discontinue CENTERA as it "was not able to meet the same safety profile as the "excellent" SAPIEN platform).

iv. The FTC did not quantify or prove substantial harm to innovation.

231. The FTC's economic expert, Dr. Wilson, did not analyze the extent to which competition between J-Valve and Trilogy is currently driving innovation. 11/24 AM (Wilson) 64:18–25. Nor did Dr. Wilson analyze the extent to which, if at all, the Transaction will reduce net expenditure in support of TAVR-AR R&D, *id* at 56:14–18, or lessen innovation, *id.* at 63:24–64:3 ("I did not perform a specific numerical calculation speaking to the amount of innovation at risk.").

232. In contrast to Dr. Wilson, Dr. Bailey did conduct an empirical analysis of Edwards' innovation incentives. 11/25 AM (Bailey) 17:17–18:3. Dr. Bailey's analysis showed that Edwards would have a [redacted],

[redacted] *Id.* at 18:13–19:20.

233. The FTC's allegations that head-to-head competition between Edwards and JenaValve drive innovation are also misplaced. The record shows that, for example, JenaValve's efforts to develop and improve Trilogy's valve sizes and expanded indications predate JC Medical's US Presence by at least seven years. JenaValve's board materials discussed the need to develop a version of Trilogy capable of treating patients with larger sized annuli since at least 2016. DX-0003 at 60; DX-0004 at 37–39; 11/18 PM (Kilcoyne) 139:6–23; 11/20 PM (Pinto) 93:3–7, 155:4–16. Those same board materials note that JenaValve needs expanded indication studies, so as to expand the treatable patient population. DX-0003 at 61; Kilcoyne (PM) 137:10–18; *id.* at 139:6–11 (the ARTIST trial was "on the mind of the management board" in 2016); 11/20 PM (Sun) 48:13–25; 50:5–10.

C. The FTC has failed to prove that the Transaction will substantially harm "competition" in clinical trials.

234. Finally, the FTC pivots to a theory that the Transaction will harm competition in clinical trials. But (1) clinical trials are not an appropriate antitrust market in which companies compete in the ordinary sense, (2) econometric analysis disproves the FTC's pricing theory, and (3) under the FTC's own definition, entry by others into clinical trials is easy.

i. Clinical trials do not involve competition in the ordinary sense and are not a proper antitrust market.

235. As discussed, before certain medical devices—like a TAVR device—can be offered commercially in the US, they require FDA approval. 11/19 AM (Wood) 58:6–9. The primary mechanism for doing that is a pivotal trial. Put differently, the pivotal trial is an experiment, the purpose of which is to obtain approval so that a device can ultimately be sold commercially. 11/25 PM (Bailey) 22:15–24; 11/19 AM (Wood) 60:10–21; DX-0138 at 5.

236. As Dr. Wilson admits, companies in pivotal trials are not trying to make a profit. PX-8001 (Wilson Rep.) ¶¶ 42, 116 ("[T]he relevant products are still in the pre-commercial stage" where "[i]t is not a priority for [developers] to maximize profits in [clinical] trials"); *see* DX-0298 (Bailey Rep.) ¶ 4 (explaining that for precommercial clinical innovators, "the potential profitability of the resulting products was not an important consideration."); 11/25 PM (Bailey) 22:15–24. Nor do they make a profit: "The cost of the clinical research far exceeds the revenue that you get for the valve and the trial." 11/19 AM (Wood) 60:3–6; 11/20 PM (Sun) 67:2–67:9. Indeed, by law, companies cannot charge sites or investigators a price for the device larger than necessary to recover the costs to manufacture, research, and develop the device. 11/21 AM (Vahl) 30:16–31:1; DX-0178; DX-0289 (Bailey Rep.) ¶¶ 62, 63 (citing 21 C.F.R. ¶ 812.7); 11/24 AM (Keltjens) 127:21–24; PX-8001 (Wilson Rep.) ¶ 116. And Edwards generally charges the same "price" regardless of whether it is the only company running a trial. Kereiakes Dep. 97:6–15.

237. Similarly, as Mr. Wood testified, companies in pivotal trials are not trying sell as many devices as possible (*i.e.* maximize output). 11/19 AM (Wood) 60:10–21. Instead, "it's all about getting your device to a commercial approval . . . you're trying to figure out, what's the minimum number of patients that I need[.]" *Id.*

238. Nor do companies like Edwards and JenaValve face a scarcity of sites. Of the more than 800 TAVR centers in the US that can perform TAVR procedures, only about 5% of these centers are currently involved in TAVR-AR trials. 11/19 AM (Wood) 59:3–60:2; DX-0289 (Bailey Rep.) ¶¶ 58–59; 11/18 PM (Kilcoyne) 141:23–142:8; 11/25 PM (Bailey) 25:7–26:6. Sites can run more than one clinical trial, including more than one pivotal trial for the *same* indication. DX-0289 (Bailey Rep.) ¶ 60, Ex. 12; 11/19 AM (Wood) 59:3–60:2; 11/20 PM (Concepcion) 37:20–38:8; 11/20 PM (Sun) 66:8–9. Similarly, the total number of principal investigators available to conduct

clinical trials exceeds the number being used by Edwards and JenaValve. 11/25 PM (Bailey) 26:3–6; DX-0289 (Bailey Rep.) ¶ 59, Ex. 11. There are also more sites interested in participating in a TAVR-AR clinical trial than there are spaces available. DX-0261; 11/19 AM (Wood) 59:23–24 ("[Y]ou end up telling a lot more people no than you tell yes.").

239. There is no competition as it is ordinarily understood in this space. Even if there were, there is no overlap between Defendants. JenaValve is currently running a pivotal trial (ARTIST) for intermediate- and low-risk patients. Edwards is currently running a pivotal trial (JOURNEY) for inoperable and high-risk patients.

240. Further, econometric analysis confirms that the Transaction has not impacted clinical-trial pricing.

241. The FTC asserts that JC Medical's provision of the J-Valve to Christ Hospital for use in J-Valve's EFS trial without charging a reimbursement rate is evidence of pre-commercial price competition. 11/18 AM (Pl.'s Opening) 28:24–29:13. But the FTC did not establish that JC Medical's reimbursement rate was driven by competition with JenaValve as opposed to some other factor. 11/24 AM (Wilson) 62:18–63:13. Nor did the FTC show that J-Valve's lower reimbursement rate exerted competitive pressure on JenaValve.

242. Dr. Bailey, by contrast, performed economic analyses demonstrating that JC Medical's enrollment of US clinical trials had no effect on JenaValve's clinical trial reimbursement rate at any stie. 11/25 PM (Bailey) 23:4–25:6. This outcome is expected as, again, clinical trials are not ordinary markets—and the econometric analysis of Dr. Bailey negates the FTC's theory of clinical price competition. 11/25 PM (Bailey) 22:5–20.

ii. Entry is easy under the FTC's theory.

243. For a Class III high-risk medical device to begin clinical testing in the United States, a developer must apply for and receive an investigational device exemption ("IDE"). DX-0289

(Bailey Rep.) ¶ 63; DX-0288 (McWilliams Rep.) ¶¶ 33–34. Seeking an IDE is the first stage of the FDA regulatory approval process. The FTC's experts admits that receipt of an IDE is the entry point for the FTC's relevant market. 11/24 AM (Wilson) 74:2–75:18; *see* 11/21 PM (Kesselheim) 16:8–13, 16:14–17:4, 46:11–47:10.

244. But the FTC's experts undertook no analysis to assess the barriers a developer would face when applying for and receiving an IDE. 11/24 AM (Wilson) 82:10–24; 11/21 PM (Kesselheim) 65:4–9, 73:8–13. Nor did either of the FTC's experts assess the time or costs associated with applying for an IDE. 11/24 AM (Wilson) 82:14–24; 11/21 PM (Kesselheim) 65:4–9, 73:8–13. Because the FDA does not disclose IDE approvals, several industry participants could be privately developing a TAVR-AR device in US human clinical trials. 11/19 AM (Wood) 50:11–19; 11/21 PM (Kesselheim) 44:1–10.

245. The record shows that, in practice, the receipt of an IDE is quick and easy. 11/19 AM (Wood) 95:14–18 (The "FDA went on a very dedicated path to try to bring early research back to the United States. So they've actually made it quite easy for people to get EFS IDEs approved in the U.S. to do research here."). Unless otherwise indicated by the FDA, an IDE application is approved after 30 days of receipt by the FDA. 11/21 PM (Kesselheim) 16:14–17:4, 46:15–20.

246. The only obstacle to receiving IDE approval is submission of pre-clinical testing. DX-0289 (Bailey Rep.) ¶ 106; DX-0288 (McWilliams) ¶¶ 33–34. But companies can—and often do—conduct such testing outside of the US. 11/21 AM (Vahl) 26:12–27:7; 11/25 AM (McWilliams) 75:12–76:15, 79:11–78:17; 11/21 PM (Kesselheim) 44:1–11, 71:7–12, 72:14–18 (it is "normal for high-risk medical devices to rely on a mixture of ex-U.S. and U.S. data for the FDA approval process" and it would be consistent with the TAVR-AS experience for TAVR-AR developers to start with trials outside the US). For example, Edwards conducted a clinical trial for SAPIEN that

involved 250 patients across Europe and Canada. DX-0289 (Bailey Rep.) ¶ 101. n. 231. Laguna Tech likewise has conducted in-human clinical trials of its ZETA TAVR-AR valve in Chile, implanting six cases in late 2023. *Id.*; Madrid (Laguna Tech) Dep. 25:23–26:08, 35:14–16; DX-0238.

247. Not only are IDE applications commonly supported by data generated outside of the US, because medical devices like TAVR-AR devices are prohibited from conducting human clinical studies without an IDE, applications for an EFS or pivotal trial *have* to be based on clinical data from outside the US. 11/21 PM (Kesselheim) 15:8–13, 44:1–19, 46:6–10, 71:8–11, 76:16–77:19; Madrid (Laguna Tech) Dep. 28:9–18, 46:22–47:3; DX-0138 at 11–12.

248. Should any of the companies currently developing TAVR-AR devices outside of the US—many of whom have clinical testing from a commercial device, EFS study, or pivotal trial—apply for an IDE, they could begin clinical trials in the United States in as little as a month. 11/20 PM (Pinto) 131:20–24; 11/25 AM (McWilliams) 79:11–80:17.

249. Upon receipt of an IDE, developers can quickly launch and complete US clinical trials. For example, from IDE approval, JC Medical was able to complete its EFS study within six months, and received FDA approval to start its pivotal trial within a year. 11/21 AM (Turco) 104:10–15; 11/21 PM (Kesselheim) 60:6–11, 68:4–5. Dr. Kesselheim was unaware of "any reason why the other companies developing TAVR-AR devices around the world couldn't get through the feasibility stage on the same timeline that JC Medical did." 11/21 PM (Kesselheim) 76:8–12; Madrid (Laguna Tech) Dep. 57:11–23, 58:1–2 ([redacted]); DX-0238 at 3; DX-0239 at 10.

D. The FTC's grab-bag of allegations regarding supposedly improper conduct are false and irrelevant.

250. Throughout the hearing, the FTC raised specters of wrongdoing, none of which help the FTC meet its burden of proof.

251. *First*, although the FTC is not bringing a claim under the Hart-Scott-Rodino Act—which authorizes pre-consummation government antitrust review for transactions over a certain threshold—it nonetheless suggested that Edwards had artificially lowered the purchase price of JC Medical to evade FTC review. 11/18 AM (Pl.'s Opening) 37:25–38:9. This is a distraction. It is also incorrect. As the FTC does not dispute, the purchase price for JC Medical was below the HSR threshold. 11/19 PM (Bobo) 135:15–18; 11/19 PM (Zovighian) 48:22–24. And as discussed above, Edwards' separate investment in Genesis was a legitimate and distinct investment. In any event, nothing requires Defendants to seek out FTC review of a transaction, which—as this case demonstrates—can be expensive, burdensome, and disruptive. *See* 11/19 PM (Bobo) 130:15–131:1.

252. *Second*, although again disconnected from any legal theory, the FTC suggests that Edwards somehow misused JenaValve's confidential information. This, too, is a distraction.

253. Upon signing the merger agreement, Edwards and JenaValve established a clean-team procedure to facilitate the exchange of sensitive information necessary for business operations in a safe and protected manner. 11/18 PM (Kilcoyne) 40:8–13. Pursuant to the clean-team agreement, information affirmatively designated by JenaValve as "clean team only" can only be reviewed by a limited number of Edwards employees approved by JenaValve. 11/18 PM (Kilcoyne) 41:3–6.

254. Edwards employees on the clean team were prohibited from having access to information or responsibilities related to JC Medical or J-Valve. 11/18 PM (Kilcoyne) 41:11–17. Should the Transaction not close, clean team members are also prohibited from working on other

TAVR-AR programs in the future. 11/20 AM (Bobo) 45:18–22. And Edwards has abided by the clean-team process. 11/24 PM (Sirimanne) 115:11–116:9.

V. The equities and public interest disfavor the FTC's requested injunction.

255. As explained further in the Conclusions of Law, merger agreements cannot live in limbo indefinitely. And the outside date for the merger agreement here is January 23, 2026. PX-1166 at 106–07. As the FTC has admitted in other cases—and as experience shows—if the Court grants the requested preliminary injunction, it may kill the merger entirely. Here, that would have dire consequences for patients.

256. Over 100,000 Americans suffer from severe symptomatic aortic regurgitation. 11/20 P.M. (Pinto) 126:18–20. Today, many of those patients cannot obtain treatment. *Id.* at 130:22–131:2. As explained above, the merger increases the likelihood that a TAVR-AR device will receive FDA approval and that such device (or devices) will be manufactured at scale, increasing patient access. It will also enhance Edwards' ability to innovate in the TAVR-AR space, combining the learnings from multiple R&D streams, and creating multiple iterations of devices for years to come that will expand patient-population indications and improve patient outcomes.

257. Further, as discussed, JenaValve [redacted] If the Transaction is blocked, JenaValve's ability to implant Trilogy at additional sites "would come to a grinding halt"—"it will be [a] crisis day one." 11/24 AM (Keltjens) 129:13–19. It would "struggle" to meet demand even at existing sites. *Id.* at 129:23–130:2; *see* Thourani Dep. 123:6–124:11 ("[I]f this [transaction] doesn't happen and JenaValve's by itself . . . we'll treat a miniscule amount of patients like we're doing now . . . [and] hurt patients . . . ."). Indeed, the delay in closing has already harmed JenaValve's ability to obtain FDA approval. DDX-001 at 14 ("If we would have been part of [Edwards] when this AWT issue came to bear, it would have been tremendously helpful and it would accelerated time to market.").

258. If the Court grants the FTC's requested injunction, it will thus harm the public interest now—by hampering JenaValve's ability to serve patients now—and in the future—by hampering the likelihood that any TAVR-AR device is approved and reducing innovation.

259. Likewise, the private equities also disfavor the requested injunction. Defendants have already spent an enormous amount of time and money negotiating and now defending the proposed transaction. They have also voluntarily held off on closing the proposed transaction for nearly six months and agreed to a Temporary Restraining Order, ECF No. 5, to give the FTC time to investigate and bring this case and to give this Court time to decide the case.

260. JenaValve, in particular, would be seriously harmed if the Transaction is blocked. The FTC's suit has already harmed employee morale and created uncertainty. 11/24 AM (Keltjens) 131:9–16. As both JenaValve's Chairman and CEO testified, JenaValve has a risk of losing key employees and may even have to lay off employees. *Id.* at 130:12–131:4; 11/18 PM (Kilcoyne) 126:23–25. And, if JenaValve is required to [redacted]. 11/18 PM (Kilcoyne) 118:20–25; *see* 11/24 PM (Keltjens) 6:20–24.

PROPOSED CONCLUSIONS OF LAW

261. A preliminary injunction is a "particularly" "extraordinary and drastic" remedy in the merger context because it "may prevent the transaction from ever being consummated." *FTC v. Exxon Corp.*, 636 F.2d 1336, 1343 (D.C. Cir. 1980).[1] This case is no different: the merger agreement's termination date is January 23, 2026. PX-1166 at 106–07. Thus, the FTC "must come forward with rigorous proof to block [this] proposed merger." *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 115 (D.D.C. 2016). Specifically, it must make a clear showing that (1) it is likely to succeed on the merits of its antitrust claim, (2) the balance of equities (both public and private) favor an injunction, and (3) an injunction is in the public interest. *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115–16 (D.D.C. 2004).

I. The FTC has failed to establish a likelihood of success on the merits.

262. To prove a claim under Section 7 of the Clayton Act, the FTC must prove that the merger is likely to substantially lessen competition. 15 U.S.C. § 18. One tool used by courts to determine if the government has done so is the framework set out in *United States v. Baker Hughes*, 908 F.2d 981, 982–83 (D.C. Cir. 1990). Under that framework, which has never been formally adopted by the D.C. Circuit outside of horizontal commercial mergers, "the Government must first establish its prima facie case by 1) identifying the relevant product and geographic market and 2) showing that the proposed merger is likely to substantially lessen competition in that market." *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 191 (D.D.C. 2018).

263. To meet its *prima facie* burden, the FTC "must make a fact-specific showing that the proposed merger is likely to be anticompetitive." *United States v. AT&T, Inc.*, 916 F.3d 1029,

[1] Unless otherwise indicated, internal quotation marks, alterations, and citations have been omitted from quotations throughout.

1032 (D.C. Cir. 2019). Importantly, Section 7 "deals in probabilities, not ephemeral possibilities." *United States v. Marine Bancorp., Inc.*, 418 U.S. 602, 622–23 (1974); *accord United States v. UnitedHealth Grp. Inc.*, 630 F. Supp. 3d 118, 129 (D.D.C. 2022). Thus, the FTC must show that the competitive harm will be "sufficiently probable and imminent." *Marine Bancorp.*, 418 U.S. at 623 n.22; *AT&T*, 310 F. Supp. 3d at 189–90. It is also not enough for the FTC to show that the merger will cause *some* competitive harm. *UnitedHealth*, 630 F. Supp. 3d at 152. Rather, it must establish that the merger will *substantially* harm competition. *Id.* And that harm must be *in* the alleged relevant market. *AT&T*, 310 F. Supp. 3d at 191.

264. If the FTC establishes its *prima facie* case, Defendants must "present evidence that the *prima facie* case inaccurately predicts the relevant transaction's probable effect on future competition" or otherwise "sufficiently discredit the evidence underlying the *prima facie* case." *Id.* If Defendants produce such evidence, "the burden of producing additional evidence of anticompetitive effects shifts to the government." *AT&T*, 916 F.3d at 1032. The amount of evidence needed to shift the burden back to the government is "relatively low." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 213 (D.D.C. 2017). In practice, though, this framework "isn't as compartmentalized as it sounds," the "framework is applied flexibly," and "evidence is often considered all at once." *FTC v. Tempur Sealy Int'l, Inc.*, 768 F. Supp. 3d 787, 813 (S.D. Tex. 2025). Importantly, the "ultimate burden of persuasion . . . remains with the government at all times." *AT&T*, 916 F.3d at 1032.

265. Ultimately, "the principal objective of antitrust policy is to maximize consumer welfare." *AT&T*, 310 F. Supp. 3d at 193. So, in determining whether the FTC has met its burden of establishing a likelihood of success under Section 7, the Court "must consider both the positive and negative impacts on consumers by balancing the proconsumer, positive elements of the merger

against the asserted anticompetitive harms." *Id.* And the Court must compare the world with the merger against the world without the merger and determine which world is better for patients. *See FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1080 (D.C. Cir. 1981); *FTC v. Nat'l Tea Co.*, 603 F.2d 694, 700 (8th Cir. 1979); *Arch Coal*, 329 F. Supp. 2d at 125; *see* 11/24 AM (Wilson) 55:17–56:8 ("[The Court must] evaluate what the merger would be likely to lead to relative to . . . the counterfactual non-merger world.").

A. The FTC is not entitled to a presumption of harm.

266. In certain cases, the FTC can use a change in market shares as a "short cut" (sometimes called a "presumption") to establish its *prima facie* case. *See AT&T*, 916 F.3d at 1032. Courts have limited this shortcut to cases where market shares "provide a proper picture of a company's future ability to compete." *Arch Coal*, 329 F. Supp. 2d at 125. For example, the D.C. Circuit has held that the presumption does not apply to vertical mergers because the merger itself yields no change in market shares. *AT&T*, 916 F.3d at 1032.

267. Likewise, the prevailing view of the economic literature and of the FTC (at least until this case) is that "there is no empirical basis for a presumption" in pre-commercial R&D cases like the one here. Statement of Chairman Muris at 23, *In re Genzyme Corp.*, No. 021-0026 (FTC Jan. 13, 2004) ("*Genzyme*");[2] *see* DX-0289 (Bailey Rep.) § 4.3.1 (collecting supporting economic literature). Put differently, in a pre-commercial R&D market there are no real market shares, and the fact that a merger combines two previously independent R&D streams tells the Court nothing about whether such combination will enhance or diminish innovation. It thus does not "provide a proper picture of a company's future ability to compete." *Arch Coal*, 329 F. Supp.

[2] https://www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./murisgenzymestmt.pdf.

2d at 125. Indeed, to apply a presumption in non-commercial cases "would have the effect of routinely blocking mergers likely to accelerate innovation," thus harming "consumer interests." *Genzyme* at 23. Accordingly, courts have only ever applied the presumption to mergers involving an existing commercial market from which market shares can be calculated. *See Fraser v. Major League Soccer, LLC*, 284 F.3d 47, 69–70 (1st Cir. 2002) (declining to apply a presumption to a market that did not yet exist). If the Court applied a presumption here, it would be the first to do so.

268. Moreover, market shares must be an accurate predictor of future competitive effect to justify a presumption. *Arch Coal*, 329 F. Supp. 2d at 125. Here, they are not.

269. *First*, the market shares calculated by Dr. Wilson do not predict future competitive force in the commercial market (because they do not predict who will receive approval) or the clinical "market" (because clinical trials are designed to end). The month-to-month variability in Dr. Wilson's market shares confirms as much. DDX-002 at 037. Dr. Wilson's market shares further fail to account for the fact that, absent the merger, one product will be supported by a company with significant resources and 20 years of TAVR experience, while the other will be supported by a struggling startup.

270. *Second*, increased market shares do not lead to reduced innovation incentives. 2B Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 407 (2025); DX-0289 (Bailey Rep.) ¶ 72. And the incentives to innovate here are significant.

271. *Third*, the FTC calculates its purported market shares based on clinical trials. But such shares are divorced from competition or future competitive abilities. Having more clinical sites does not indicate a better chance of FDA approval or better ability to scale. To the contrary, having to extend clinical trials or run additional clinical trials could instead show that the clinical

trials have *not* gone well and more evidence must be developed. Further, clinical trials are naturally designed to end, so even to the extent competition in clinical sites occurs, current shares do not predict future competitive presence.

272. The FTC also asks this Court to enjoin the merger without assessing competitive harm because it "tends to create a monopoly." 11/18 AM (Pl.'s Opening) 26:13–15. First, this is not a merger to monopoly. Second, the "tends to create a monopoly" language does not, as the FTC claims, create liability regardless of competitive effect. Rather, the "tends to create a monopoly" language merely ensures that the Clayton Act applies to vertical mergers as well as horizontal mergers. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 590–91 (1957). It does not relieve the FTC of its burden of showing harm to competition. *See id.* at 605–06 (identifying harm to competition).[3]

273. *Fourth*, the FTC claims that the merger violates Section 7 because it eliminates direct competition. 11/18 AM (Pl.'s Opening) 28:24–29:1. That is wrong on the facts. It is also wrong on the law, *Malaney v. UAL Corp.*, No. 10-cv-02858, 2010 WL 3790296, at *7 & n.11 (N.D. Cal. Sept. 27, 2010), *aff'd*, 434 F. App'x 620 (9th Cir. 2011) ("[The argument] that any non-trivial acquisition of a significant rival is per se violative of the Clayton Act is wrong."). The elimination of head-to-head competition does not obviate the need to prove that the merger is likely to *substantially* lessen competition. *See United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 43–44 (D.D.C. 2017).

[3] The FTC relies on *FTC v. Alliant Techsys. Inc.*, 808 F. Supp. 9, 20–21 (D.D.C. 1992). But in *Alliant*, the FTC proved that the merger would increase prices. *Id.* at 21.

274. Because the FTC cannot rely on a presumption to meet its burden, it "must make a fact-specific showing that the proposed merger is likely to be anticompetitive." *AT&T, Inc.*, 916 F.3d at 1032. It has not done so.

B. The FTC failed to establish a valid relevant market.

275. The FTC must establish a valid relevant market. *Marine Bancorp.*, 418 U.S. at 618. "[T]his burden is on the FTC alone," and Defendants need not offer or prove an alternative relevant market. *Tempur Sealy*, 768 F. Supp. 3d at 815; *accord FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 291–92 (D.D.C. 2020). The failure to establish a valid relevant market is dispositive. *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1053 (8th Cir. 1999).

276. The relevant product market must include all products "reasonably interchangeable by consumers for the same purpose." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956). It must "correspond to the commercial realities of the industry." *Brown Shoe Co. v. United States*, 370 U.S. 294, 336–37 (1962). "[T]he FTC can't use invalid markets to gerrymander its way to victory." *Tempur Sealy*, 768 F. Supp. 3d at 827; *accord United States v. Booz Allen Hamilton, Inc.*, No. 22-cv-1603, 2022 WL 9976035, at *10 (D. Md. Oct. 17, 2022); *see United States v. U.S. Sugar Corp.*, 73 F.4th 197, 205 (3d Cir. 2023) (rejecting the government's "purely self-serving" market definition). But that is precisely what the FTC has done here.

277. At a minimum, the FTC's proposed market excludes surgical artificial valve replacement (or SAVR). But SAVR is the only treatment currently available for the patients the FTC claims to represent. It is also a safe and effective option for intermediate- and low-risk patients. Yet, despite the fact that products need only be reasonably interchangeable to be in the same market, and for intermediate- and low-risk patients SAVR clearly is interchangeable, the FTC never addresses this fact. *See Tempur Sealy*, 768 F. Supp. 3d at 815 (holding that "perfect fungibility isn't required" for products to be in the same market).

278. This yields a significant failure for the government. The FTC's theory requires SOJOURN and Trilogy to be the *only* available options for patients so that they can allege a "merger-to-monopoly." But an estimated 40–60% of severe symptomatic AR patients are at intermediate or low risk, and thus have an alternative to Defendants' valves—SAVR. The FTC never addresses this reality, nor did Dr. Wilson account for it in his market-share calculations. Thus, for 40–60% of the AR patients at issue in the FTC's case, the FTC has no proof of any harm at all. *See also Tempur Sealy*, 768 F. Supp. 3d at 860–61 (holding that the FTC's total failure to offer any evidence about the merger's likely effect on the majority of customers supported denying preliminary injunction).

279. The FTC goes further and excludes transapical TAVR-AR devices. PX-8001 (Wilson Rep.) ¶ 27 ("[W]hen I discuss TAVR-AR products, I am referring to transfemoral ones unless specifically noted."). But these are definitionally TAVR-AR devices used to treat the same disease. Such devices can be deployed either transapically or transfemorally and a transapical system can become a transfemoral system. 11/24 PM (Sharma) 136:20–137:20. The FTC apparently excludes transcatheter valve-*repair* devices, even though those are also used to treat AR. 11/18 PM (Kilcoyne) 14:3–17; 11/20 AM (Bierman) 109:21–110:14. And the FTC excludes devices not currently in pivotal trials. *See* 11/18 AM (Pl.'s Opening) 24:7.

280. Conveniently, after the dust settles, only Edwards and JenaValve are left in the FTC's proposed market. *See id.* at 22:6–25, 24:17–19. Because the FTC's entire case rests on the idea that this is a "two-to-one merger-to-monopoly," 11/18 AM (Pl.'s Opening) 14:20, the FTC did not craft a relevant market that would reflect commercial realities but instead started with a market limited to Defendants and then impermissibly "worked backwards." *Tempur Sealy*, 768 F. Supp. 3d at 827.

i. The FTC's novel, pre-commercial product-market definition should be rejected.

281. Section 7 requires a "line of commerce," 15 U.S.C. § 18, *i.e.*, a relevant product market, *Brown Shoe*, 370 U.S. at 325. A relevant product market must be based on "commercial realities." *Id.* at 336; *see FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 48 (D.D.C. 2015) (noting, too, that the product market must be "economically significant"). But neither SOJOURN nor Trilogy (the devices on which the FTC's market centers) are approved for commercial sale. In fact, there are no commercially available TAVR-AR devices in the United States, and it is unclear when or even if there ever will be such a device. Defendants are unaware of any case blocking a merger where there is no commercially available product at issue, and at least two courts have rejected similar attempts. *See Fraser*, 284 F.3d at 69–70; *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1211 (2d Cir. 1981).

282. The best support the FTC can muster for its novel pre-commercial challenge is one out-of-circuit case: *Illumina, Inc. v. FTC*, 88 F.4th 1036 (5th Cir. 2023). 11/18 AM (Pl.'s Opening) 21:19–24; Mot. 25. There, the acquirer (Illumina) made a commercially available next-generation-sequencing platform. *Illumina*, 88 F.4th at 1044. The seller (Grail) made a commercially available multi-cancer-early-detection test. *Id.* Other companies were developing similar tests and were expected to hit the market "soon." *Id.* at 1045. Grail's detection test, and those being developed by others, relied on Illumina's platform as an input and had "no available alternatives." *Id.* at 1044–45. The FTC argued that, because of the merger, Illumina would be incentivized to withhold its platform from Grail's competitors, thus preventing them from developing their own tests. *Id.* at 1045. The FTC brought its case in-house and the Fifth Circuit reviewed that decision under a highly deferential "substantial evidence" standard, by which the FTC did not have to meet a normal evidentiary burden; the court was instead "bound" by "factual determinations" even if an alternative was "equally or even more reasonable and persuasive." *Id.* at 1046.

283. *Illumina* is inapposite. There, the FTC brought a vertical challenge based on the alleged effect of withholding an existing commercially available essential input from downstream R&D streams. Here, the FTC brings a horizontal challenge based on the alleged effect of combining two R&D streams. There, both products at issue (next-generation-sequencing platforms and multi-cancer-early-detection tests) were already commercially available. Here, the FTC's merger challenge involves a product for which there is no existing commercial market. There, the competitor products at issue that had not yet been commercialized did not require FDA approval, *Id.* at 1045 n.1, and the evidence established that they would be entering the market "soon," *id.* at 1045. Here, any TAVR-AR device would require approval from the FDA (whom the FTC did not call and from whom the FTC gathered no evidence) and the evidence shows that it is unclear whether (much less when) any TAVR-AR device would receive approval. There, the Fifth Circuit reviewed the FTC's in-house decision under a highly deferential standard. Here, the Court must independently assess the FTC's request for the "extraordinary and drastic" remedy of a preliminary injunction and find that the FTC has met its burden of proof.

284. The fact that, in the 111 years since the Clayton Act was enacted, *Illumina* is the closest case the FTC can find touching on a pre-commercial market merely demonstrates how shaky the FTC's theory is. If this Court endorses the FTC's product market (based solely on pre-commercial products) and theories of competitive harm, it would be the first ever to do so.

ii. The FTC's relevant-market definition is mismatched with its theories of harm.

285. Because the relevant market is a tool for assessing the impact on competition, the "market definition must be relevant to the theory of harm at issue." *In re Google Play Store Antitrust Litig.*, 147 F.4th 917, 935 (9th Cir. 2025); *Brown Shoe*, 370 U.S. at 324 (explaining that whether a merger *substantially* lessens competition "can be determined only in terms of the market affected"). In other words, the government must prove that the merger will harm competition "*in*

the relevant market." *AT&T*, 916 F.3d at 1032 (emphasis added). Often, this means the FTC will need multiple markets corresponding to multiple theories of harm. For several reasons, the FTC's markets fail.

286. Here, the FTC raises three distinct theories of harm in three distinct markets: (1) a future commercial market, (2) a market for innovation, and (3) competition in a market for clinical trials. Yet, rather than attempt to prove each of these markets, the FTC alleges a single market: TAVR-AR devices (but effectively limited to just Trilogy and SOJOURN). But that single definition ignores the commercial realities and competitive contours of each of the FTC's theories.

287. *First*, the FTC claims that the merger will harm competition in a future commercial market for TAVR-AR. It is undisputed that neither SOJOURN nor Trilogy have commercial approval today. And as discussed below, the FTC did not prove that SOJOURN and Trilogy are likely to both be approved. In fact, the undisputed record is that the likelihood of both being approved is less than 50%. Nor did the FTC prove that, on the timeline the FTC's theory of harm requires, the myriad other devices in development will not be approved. Thus, a market definition limited to SOJOURN and Trilogy ignores the reality of a future commercial market.

288. *Second*, the FTC claims that the merger will harm TAVR-AR innovation. But the area of effective competition for TAVR-AR innovation is every company working on a TAVR-AR device, including those outside the US. Indeed, Edwards' own ordinary-course documents recognize this as the "competitive landscape." And, as discussed further below, Edwards responds to this competitive pressure—and to pressure to expand indications to treat more patients, as well as pressure from the companies it views as fast followers—regardless of whether the device is in the US or what stage of development it is in. Thus, a market definition limited to SOJOURN and Trilogy ignores the current competitive realities of innovation.

289. *Third*, the FTC claims that the merger will harm competition in the "market" for clinical trials for TAVR-AR. But this is not a market in any meaningful sense. As discussed, firms in clinical trials are not profit-maximizing or output-maximizing and prices are regulated. Further, patients have no choice in the device that they receive via a clinical trial. A patient is enrolled in one trial or the other. In fact, patients cannot qualify for *both* ARTIST and JOURNEY—Defendants' respective ongoing trials—because one only applies to high-risk patients and the other only applies to intermediate- and low-risk patients. Thus, clinical trials bear no relation to an antitrust relevant market, which considers things like what a "profit-maximizing" firm would do (HMT), consumer choice in response to price changes (cross-elasticity of demand), or consumer sensitivity to price changes (*Brown Shoe* indicia). Moreover, the FTC defined its market based on reasonable substitutes for *patients* needing AR treatment. 11/18 AM (Pl.'s Opening) 22:15-23:5. But the *doctors* running clinical trials are not limited to treating a particular disease. DX-0289 ¶ 58; Thourani Dep. 118:4–6; 11/18 PM (Kilcoyne) 141:23–142:8; 11/25 PM (Bailey) 25:7–26:2, 26:3–6. The FTC's clinical-trials theory must focus on the doctors "who will feel the impact of any price increase," and the FTC's "incorrect focus reflects a misunderstanding" of the market that dooms its theory. *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 339, 342 (3d Cir. 2016).

iii. The FTC failed to adequately support its gerrymandered product market.

290. Even if the Court considers the FTC's TAVR-AR market on its own, disconnected from the specific theories of harm, the FTC has failed to prove a relevant market.

291. The FTC attempts to justify its product-market definition with a "hypothetical monopolist test" conducted by its expert, Dr. Wilson. PX-8001 at 22–28; 11/24 AM (Wilson) 17:23–22:7, 23:3–26:4. But despite elsewhere acknowledging that quantitative analysis is more reliable, Dr. Wilson did not conduct any quantitative analysis or use any data at all. Instead, he merely relied on anecdotes about competition. *See* PX-8001 ¶¶ 43–50; 11/25 AM (Bailey) 6:18–

7:4. And when courts use a hypothetical monopolist test to define a market, it is a *quantitative* analysis that "requires a reliable data set." *Tempur Sealy*, 768 F. Supp. 3d at 827.

292. Moreover, the hypothetical monopolist test asks "whether a hypothetical *profit-maximizing firm, not subject to price regulation*, that was the only present and future seller" of a product could profitably impose a "small but significant non-transitory increase in price." *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 52 (D.D.C. 2011) (emphasis added). So to perform the test, Dr. Wilson assumes in a footnote of his report that the firms are profit maximizing. But that assumption directly contradicts the statement in his report that for products in clinical trials, like SOJOURN and Trilogy, "it is not a priority for [a] firm to maximize profits." PX-8001 ¶ 116; *see* 11/19 AM (Wood) 60:3–6.

293. The FTC also attempts to justify its proposed market with the *Brown Shoe* practical indicia. To begin, the FTC offered no evidence or argument regarding several of these factors: unique production facilities, sensitivity to price changes, or specialized vendors, "thus conceding their inapplicability." *Tempur Sealy*, 768 F. Supp. 3d at 815; *see* PDX-001 at 23. Indeed, if anything, these indicia undermine the FTC's proposed market. For example, rather than showing specialized vendors, the evidence showed that Edwards sells surgical valve replacement and TAVR devices and devices that can be used both transapically and transfemorally. *See* 11/20 AM (Bobo) 36:8–24; 11/24 PM (Sharma) 137:6–23. The lack of specialized vendors thus undermines the FTC's market. The few indicia that the FTC did argue do not support its market definition.

294. *Industry or Public Recognition*: As discussed above, the documents relied on by the FTC in fact refute the FTC's market, including all TAVR-AR devices in the competitive landscape. *See FTC v. Tapestry, Inc.*, 755 F. Supp. 3d 386, 430 (S.D.N.Y. 2024) (companies in an industry usually have "accurate perceptions of economic realities" of that industry). The FTC came

nowhere close to offering the "clear evidence" required that the industry participants recognize its proposed market definition. *Tempur Sealy*, 768 F. Supp. 3d at 818.

295. *Peculiar Characteristics and Uses*: As discussed, the FTC made no effort to show that SOJOURN and Trilogy have different characteristics or uses from the various other TAVR-AR devices in development.

296. *Distinct Customers*: The FTC argues that, because Defendants' documents "focus on people with severe, symptomatic AR," this constitutes a distinct customer base for TAVR-AR devices. 11/18 AM (Pl.'s Opening) 23:2–3. This misses the mark. The question is whether the customers for the FTC's proposed product market (*i.e.*, SOJOURN and Trilogy) are distinct from the customers for the products excluded from the FTC's proposed product market (*i.e.*, surgical valves and non-Defendant TAVR-AR devices) such that it would support distinct markets. But the FTC offered no such evidence.

297. *Distinct Prices*: This factor is designed to assess whether there are significant price differentials between different products, which could suggest that they are in different product markets. *Tempur Sealy*, 768 F. Supp. 3d at 823. But the FTC offered no such comparative-pricing evidence, instead relying solely on a placeholder due-diligence document.

298. In sum, the FTC failed to adequately support its proposed product market, even if considered on its own terms.

iv. The FTC's geographic-market definition is contradicted by the evidence.

299. The geographic market must align with "the area of effective competition." *Brown Shoe*, 370 U.S. at 324. It must "correspond to the commercial realities of the industry and be economically significant." *Id.* at 336–37.

300. Because the life cycle for product development in this space takes many years, Edwards must consider potential innovation competitors no matter where they are located or what stage of development their device is in.

301. Edwards' ordinary-course "competitive landscape" analyses show that, particularly for innovation, the area of effective competition includes all TAVR-AR devices, no matter where they are currently being developed and no matter the stage of development. This makes sense. A US company (like Medtronic, Boston Scientific, or Abbott) could purchase a device being developed abroad and then seek FDA approval in the US—just like Edwards did with JC Medical. Or a company developing a TAVR-AR device abroad could itself bring that device to the US and seek FDA approval—just like JenaValve (originally a German company) did with Trilogy.

C. The FTC has not shown that the Transaction is likely to substantially lessen competition.

302. Although the FTC attempts to pass this case off as a run-of-the-mill horizontal merger challenge, it in fact asks this Court to do what no other court has ever done: block a merger that combines two complementary R&D streams for a product that is not yet commercially available. The FTC alleges three theories of harm; all are meritless.

303. *First,* the FTC asks the Court to find that the merger will harm competition in a potential future commercial market between two products that do not yet have FDA approval to be sold commercially and that are not predicted to receive such approval for many years (if at all). No court has ever endorsed such a theory—which is unsurprising considering the Supreme Court's instruction that Section 7 challenges be limited to harm that is "imminent." *Marine Bancorp.*, 418 U.S. at 623 n.22.

304. *Second*, the FTC asks the Court to find that the merger will harm the parties' incentive to innovate by gerrymandering the market and then and ignoring: Edwards' internal

ordinary-course documents (predating the acquisitions themselves) expressing the need to innovate quickly to stay ahead of fast followers; Edwards' incentive to expand the customer base through expanded indications and valve sizes; and Edwards' demonstrated commitment to innovation in the TAVR space.

305. *Third*, the FTC asks the Court to find that companies somehow compete in *clinical trials*, something no court has ever endorsed and which would expand Section 7 into the FDA regulatory space, inevitably chilling innovation.

i. The Transaction's procompetitive effects are central to the FTC's burden of proof.

306. All of the FTC's theories of harm assume a robust, competitive, scaled JenaValve that has somehow fixed its persistent manufacturing and quality issues and managed to secure FDA approval. This JenaValve, the FTC says, will exert substantial competitive pressure on Edwards, both in terms of innovation and in a future commercial market. But the evidence showed that this JenaValve does not exist and on its own would not exist. JenaValve's serious limitations and its inability to compete in the way the FTC speculates prevent the FTC from meeting its burden. *United States v. General Dynamics Corp.*, 415 U.S. 486, 508 (1974) (holding that the seller's "inadequate [capabilities] went to the heart of the Government's . . . prima facie case"); *Arch Coal*, 329 F. Supp. 2d at 155–57 (relying on seller's limited capabilities in holding that the FTC had failed its burden); *Nat'l Tea*, 603 F.2d at 689–99 (same); *accord New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 217–18 (S.D.N.Y. 2020) (same) ("*T-Mobile*").

307. Instead, the FTC tries to shift its burden to Defendants, claiming that JenaValve's limitations amount to a so-called "failing firm defense." This is an affirmative defense whereby, even if the government has proven that the merger will substantially lessen competition, the defendants can still win by showing that the seller was about to go out of business. *See General Dynamics*, 415 U.S. at 507–08. But the FTC is wrong to suggest that the Court can only consider

the seller's competitive capabilities—or the lack thereof—within the framework of the failing-firm defense. The Supreme Court squarely rejected that argument in *General Dynamics*, holding instead that the seller's lack of competitive capabilities "went to the heart of the Government's . . . prima facie case." *Id.* at 523.

308. Rather than showing a substantial lessening of competition, the evidence demonstrated that the Transaction will benefit competition and patients. The merger will maximize the chances of a TAVR-AR device receiving FDA approval and that any such device will be scalable and available to a larger number of patients, thus increasing output. DX-0136 at 11; 11/20 PM (Pinto) 150:7–11; 11/20 AM (Bierman) 91:5–15. It will enhance Edwards' abilities to innovate, just as Edwards' prior acquisition of a different company did in TAVR-AS. 11/18 PM (Wood) 62:18–63:6; *see also Tempur Sealy*, 768 F. Supp. 3d at 855 ("Natural experiments are relevant to the merger analysis."). It will enhance competition by paving the way for other companies. DX-0043 at 13, DX-0053 at 22. And all of this will result in more devices and better outcomes for patients with aortic regurgitation. 11/18 PM (Kilcoyne) 75:5–11.

309. The FTC tries to brush aside all of this, arguing that Defendants are seeking an exception from the antitrust laws based on benefit to patients. 11/18 AM (Pl.'s Opening) 26:25–27:2. Not so. The merger's benefits are classic *antitrust* benefits that courts consider. Also, the purpose of the antitrust laws "is to maximize consumer welfare," *AT&T*, 310 F. Supp. 3d at 193, and the FTC can obtain an injunction only if it would be in the "public interest," 15 U.S.C. § 53(b). Against that backdrop, the FTC's claim that this Court must blind itself it to the merger's likely positive, life-saving impact on patients should be rejected. 11/18 AM (Pl.'s Opening) 27:3–9.

310. The FTC again tries to shift its burden to Defendants, arguing that evidence of the merger's effects on competition and patients—which are relevant to the FTC's own *prima facie*

case—may only be considered as an "efficiencies defense." 11/18 AM (Pl.'s Opening) 33:18–34:13. But the FTC's theory of the case is that the merger will reduce output, harm innovation, eliminate all competitors, and ultimately harm patients. 11/18 AM (Pl.'s Opening) 14:17–20, 27:9–14. The fact that the evidence refuted each of these theories does not suddenly shift the FTC's burden to Defendants. *See AT&T*, 916 F.3d at 1032 ("[The] burden of persuasion . . . remains with the government at all times."); *Hadar v. Concordia Yacht Builders*, 886 F. Supp. 1082, 1089 (S.D.N.Y. 1995) ("A defense is not affirmative where it merely negates an element of the plaintiff's prima facie case."). As the Eighth Circuit explained in *FTC v. Tenet Health Care Corp.*, even if the defendants could not mount an "efficiencies defense," the procompetitive benefits of the merger and the "enhanced efficiency" of the merged firm still had to be considered "in the context of the competitive effects of the merger." 186 F.3d at 1054.

311. But even if the Court applies an efficiencies-defense framework, the benefits of the merger are cognizable. *First*, the benefits of the merger are "merger-specific," meaning they "cannot be achieved by either company alone." *T-Mobile*, 439 F. Supp. 3d at 210. Notably, the fact that benefits could be achieved without a merger does not defeat merger specificity if those benefits could not be achieved as quickly or to the same degree. *Id.* at 211–13.

312. Here, the evidence established that JenaValve is incapable of effectively scaling or resolving its persistent manufacturing and quality issues or commercializing to the same extent as Edwards without the merger. The FTC's speculation to the contrary is of no avail. *See T-Mobile*, 439 F. Supp. 3d at 212 ("Considering the significant uncertainty surrounding [the standalone benefits predicted by the government], the Court is not persuaded that it promises nearly the same efficiencies as the Proposed Merger."). As is FTC's unsupported speculation that JenaValve could

be purchased by some other company at some time in the future. *See T- Mobile*, 439 F. Supp. 3d at 212–13 (rejecting same argument as "speculative" considering prior "failed" negotiations).

313. *Second*, the evidence established that the merger's procompetitive benefits are "verifiable," which means not unduly speculative. *Id.* at 213. Benefits may be "substantiated by analogous past experience." *Id.* Edwards' analogous experience with TAVR-AS verifies that it could do the same here. *See id.* at 216–17 (relying on prior T-Mobile merger and subsequent results in determining that procompetitive effects were sufficiently verifiable).

314. *Third*, and unlike in other litigated matters, the FTC does not question either the greater capability of Edwards to accelerate and enhance the launch of Trilogy or its incentive to do so. This is not a case where efficiencies arise from cost cutting which may or may not occur, and which may or may not be passed on to purchasers at a later date. *FTC v. H.J. Heinz*, 246 F.3d 708, 720 (D.C. Cir. 2001). This acquisition would result in a straightforward application of superior capabilities to maximize the potential uptake of a medical device for thousands of high-risk patients who have no alternative. To reject the benefits, the Court would need to believe that Edwards does not have greater capabilities and is not interested in profit-maximization, which are both implausible. As Chief Judge Boasberg recently cautioned, because "[c]ourts presume sophisticated corporations act rationally," government antitrust arguments premised on economically irrational behavior are suspect. *FTC v. Meta Platforms, Inc.*, --- F. Supp. 3d ----, 2025 WL 3458822, at *16 (D.D.C. Dec. 2, 2025).

315. After asserting that JenaValve will become a better competitor than it has ever been or could be on its own, the FTC assumes the opposite of Edwards, arguing that without JenaValve—a tiny startup—as a competitor, Edwards will suddenly stop innovating and competing. In analyzing a merger, courts often look to "[n]atural experiments." *Tempur Sealy*, 768 F. Supp. 3d

at 855 (quoting *UnitedHealth*, 630 F. Supp. 3d at 143); *see AT&T*, 310 F. Supp. 3d at 215. Here, the obvious natural experiment to determine how TAVR-AR will develop is TAVR-AS. 11/25 AM (Bailey) 150:7–14. The evidence from that natural experiment overwhelmingly shows that, even absent competition, Edwards innovated, expanded patient indications, and developed new generations of devices. Likewise, the evidence showed what happens when Edwards develops a commercial TAVR market: numerous other companies followed it into the market, the same outcome that Edwards' and third parties' ordinary-course analyses suggest is likely to happen here.

ii. The FTC did not prove that the Transaction is likely to substantially harm competition in a hypothetical future commercial market for TAVR-AR.

316. The FTC argues that the merger will harm competition in a potential future commercial market for TAVR-AR devices in the US that does not yet exist. This theory of harm is novel. *FTC v. Atl. Richfield Co.*, 549 F.2d 289, 294 (4th Cir. 1977) (novelty of FTC's theory alone could warrant denying requested injunction). No court has ever blocked a merger based on predicted harm in a market that does not yet exist.[4] *See Fraser*, 284 F.3d at 71 (impossible to predict how market would develop).

317. The closest doctrine to the FTC's theory is the actual-potential-competition doctrine, which applies when a firm enters a market via acquisition of an existing participant rather than on its own. *See FTC v. Meta Platforms Inc.*, 654 F. Supp. 3d 892, 925 (N.D. Cal. 2023). The doctrine

[4] The FTC's reference to *Polypore*, *El Paso*, and *Illumina* underscore the point. Reply 4. Each of those cases concerned an existing commercial market, and none of those cases involved the level of speculation required here. In *Polypore*, the target had acquired the equipment needed to make the relevant product and entered into preliminary agreements with customers. *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1214–15 (11th Cir. 2012). In *El Paso*, the target had bid, albeit unsuccessfully, for the only contract in the market. *United States v. El Paso Nat. Gas Co.*, 376 U.S. 651, 661 (1964). And in *Illumina*, the acquiror and acquiree both had commercialized their products. *Illumina*, 88 F.4th at 1045.

has never been endorsed by the Supreme Court. *Id.* The courts that have allowed it require proof of a likelihood "noticeably greater than fifty percent" that the firm would have entered the market without the merger. *Id.* at 927; *see also Atl. Richfield*, 549 F.2d at 294 (requiring near certainty of entry). Here, the FTC's burden is heavier still because—unlike other actual-potential-competition cases—there are *no* products yet commercialized. So, the FTC's theory requires that *both* Trilogy *and* SOJOURN will receive FDA approval. *See Genzyme* at 14 (explaining that purported anticompetitive harms regarding merging two R&D streams are only relevant if both programs ultimately succeeded). No court has ever permitted such speculation. In any event, the evidence showed that the chance that *both* Edwards and JenaValve obtain FDA approval is less than 50%. DX-0289 ¶ 54. That is not enough for the FTC to meet its burden. *See Rambus Inc. v. FTC*, 522 F.3d 456, 466–67 (D.C. Cir. 2008).

318. Moreover, the FTC's claim depends on the actions of the FDA. But courts do not assume that regulatory bodies will make particular decisions without evidence. For example, in *City of Pittsburgh v. W. Penn Power Co.*, the Third Circuit rejected a Section 7 claim alleging that a merger ended future competition between two power companies that did not currently have regulatory permission to operate in the same area. 147 F.3d 256, 267–68 (3d Cir. 1998). The court concluded that "[t]he presence of the regulatory scheme and the need for approval" doomed the antitrust claim because "as a matter of law, the court cannot conclude that the loss of potential competition was causally related to the decision of the two power companies to merge" and the city's speculation of what it "*hoped would occur*" in the future was insufficient to support a Section 7 claim. *Id.* Indeed, assuming FDA approval is particularly inappropriate here considering the recent deficiency letter.

319. Even assuming Trilogy receives FDA approval in the near term, the evidence showed that SOJOURN will reach the market in 2029 at the earliest. Dr. Wilson testified that there would only be harm if Edwards obtained *durable* monopoly power, *i.e.* power lasting 2–5 years or more. 11/24 AM (Wilson) 52:14–21. Taken together, that means the harm the FTC has purportedly identified—Edwards' ownership of two FDA-approved TAVR-AR devices—would occur in 2031 at the earliest. Section 7 does not permit speculation so far into the future. *Marine Bancorp.*, 418 U.S. at 623 & n.22 (harm must be "imminent" so as to avoid blocking a merger on "ephemeral possibilities"); *Meta*, 654 F. Supp. 3d at 926, 934 ("near future"); *Mercantile Texas Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981).

iii. The FTC did not prove that the Transaction is likely to substantially harm innovation.

320. The FTC has failed to establish that the acquisition will substantially harm innovation. Defendants are unaware of any court blocking a merger based on the theory that combining two R&D streams would harm innovation. The FTC's theory of innovation harm here ignores the relevant market for innovation, economic literature on innovation, and Edwards' numerous incentives to innovate.

321. The FTC's failure to establish a viable product and geographic market is felt profoundly in the innovation context. The FTC ignores that the area of effective competition for innovation is global. Anyone working on an AR device impacts Edwards' incentive to innovate and Edwards is closely tracking these competitors no matter where they are and regardless of whether they have begun a US pivotal trial.

322. The FTC also ignores the relevant incentives to innovate. The FTC relies on a structural presumption that assumes the risk of anticompetitive effect increases as market concentration increases. *Heinz*, 246 F.3d at 715. That may be true for existing commercial markets,

but quantitative and qualitative evidence both show that the relationship between market structure and innovation is contested and uncertain for R&D markets.[5]

323. Determining the likely effects on innovation of an *R&D merger* requires a fact specific analysis of the merging parties' incentives. *Genzyme* at 3–6. Here, the FTC assumes Edwards innovates only because of competition with JenaValve. But the evidence clearly establishes that there are multiple incentives that drive innovation that have nothing to do with JenaValve. *Booz Allen*, 2022 WL 9976035 at *7 (government's theory of harm cannot "ignore other incentives encouraging [acquiror's] vigorous competition"); *id.* ("Analyzing one changed incentive is only part of the picture, so the court must consider the broader context surrounding the Proposed Acquisition.").

324. *First*, Edwards is "highly incentivized" to innovate so that it can grow the total addressable market through indication expansion and developing devices that can treat as many patient anatomies as possible. 11/25 AM (Bailey) 101:8–16; *see Booz Allen*, 2022 WL 9976035, at *7 (crediting the parties' "[t]angible financial incentives"). Edwards' analogous experience in AS provides a natural experiment for their incentive to grow the addressable market. Edwards was first to the TAVR-AS market in the United States and began innovating before other strategics had entered the market. *See FTC v. Microsoft Corp.*, 681 F. Supp. 3d 1069, 1092–93 (N.D. Cal. 2023); *Booz Allen*, 2022 WL 9976035 at *8.

325. Edwards has continued innovating for 20 years, expanding into new patient indications, improving patient outcomes, and growing the market. DX-0220 at 5; DX-0282 at 18.

[5] FTC Staff Report, Anticipating the 21st Century: Competition Policy in the New High Tech, Global Marketplace, Vol. I, ch. 7, at 16 (May 1996) ("[E]conomic theory and empirical investigations have not established a general causal relationship between innovation and competition.").

The incentive to do so is simple: earn revenue for helping patients that were not being helped before. *See Genzyme* at 12 ("Regardless of [competitor's] program, Genzyme's incentive was to get a . . . therapy to market sooner rather than later to earn profits."). Testimony and ordinary-course documents confirm that Edwards plans to do the same for AR. 11/24 PM (Sharma) 127:21–128:6; *id*. at 140:18–20; DX-0220 at 23 ("We expect the aortic regurgitation journey to be similar to TAVR"); *see Booz Allen*, 2022 WL 9976035 at *8 (crediting defendants' theory of relevant incentives because it explained past behavior).

326. *Second*, another post-merger incentive for Edwards to continue investing in both product platforms is the significant uncertainty that each differentiated platform faces with respect to regulatory approval and scalability—uncertainty that is commonplace in early-stage settings where efficacy and safety remain unestablished. This uncertainty means that Edwards has a strong incentive to maintain and develop both platforms to maximize the likelihood of eventual commercial success.

327. *Third*, because development cycles for TAVR-AR devices are lengthy, ranging from 5–7 years, companies like Edwards cannot wait until other companies enter to innovate. They must constantly innovate to stay ahead. Courts recognize that a potential competitor's presence on the edge of the market can exert competitive effect and assess that effect based on the *subjective* perception of firms in the market, not whether those companies actually intend to enter. *Meta*, 654 F. Supp. 3d at 938–39 (citing *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 533–36 (1973)). Similarly, here, the presence of many startups that could obtain an IDE and begin a US clinical trial to catch up to SOJOURN in a relatively quick time frame supply this incentive. What matters for Edwards' incentive to innovate is that Edwards *thinks* they *may* enter, not incontrovertible proof that they will. Here, Edwards is certainly anticipating such entry.

328. *Fourth*, continuous innovation is part of Edwards' "DNA" as a company. 11/19 AM (Zovighian) 88:15–18; 11/24 PM (Sirimanne) 98:2–4. The FTC's assumption that Edwards would stop innovating post-merger would "essentially repudiate [Edwards'] entire public image" and is implausible. *T-Mobile*, 439 F. Supp. 3d at 237; *see Booz Allen*, 2022 WL 9976035 at *8 (rejecting government's theory of parties' competitive incentives as incompatible with reality).

329. Against all these continued incentives to innovate, the FTC points to just one lessened incentive: Edwards will have one less competitor to worry about. But the FTC ignores all the other remaining TAVR-AR innovators, and even then, the FTC does not grapple with the weight of JenaValve's continued competitive impact in light of the deficiency letter and [redacted] 11/18 AM (Pl.'s Opening) 28:14–18; *see Booz Allen*, 2022 WL 9976035 at *7–8 (faulting government for failing to balance all relevant competitive incentives).

330. Even if the FTC established a reduced incentive to innovate, it would need to establish that harm is *substantial* in light of *all the incentives* to innovate; the FTC made no attempt to do so. *UnitedHealth*, 630 F. Supp. 3d at 152 (government cannot assume that reduced incentive to innovate automatically leads to substantial loss of competition).

iv. The FTC did not prove that the Transaction is likely to substantially harm "competition" in clinical trials.

331. Unable to show harm to a future commercial market or innovation, the FTC makes a last-ditch pivot to a theory that the Transaction will harm "competition" in clinical trials.

332. *First*, the Clayton Act is primarily concerned with whether a proposed merger will negatively impact price and output, resulting in a substantial lessening of competition. 4 Areeda & Hovenkamp, Antitrust Law ¶ 910f (2025); *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 208–209 (D.D.C. 2018). But Dr. Bailey established that the merger will have no impact on clinical-trial pricing. 11/25 PM (Bailey) 24:14–25:6. Dr. Wilson conceded that firms in clinical trials are not

profit maximizing. And Mr. Wood testified that firms in clinical trials are not trying to maximize output, nor meaningfully compete for trial sites. Trial sites are not scarce and are often shared. In fact, the parties together have used only 19.8% of available trial sites, and 14% of principal investigators.

333. *Second*, even if clinical trials were a market, the parties are in clinical trials for different patient groups. Edwards is currently running a pivotal trial for inoperable and high-risk patients, but JenaValve is not. JenaValve is currently running a pivotal trial for intermediate- and low-risk patients, but Edwards is not. Thus, even if there was competition between pivotal trials generally, there would not be competition between Edwards and JenaValve, whose pivotal trials are aimed at different patient populations.

334. *Third*, the FTC admits that new entry "within two to three years" and low barriers to entry would disprove its allegations of clinical-trial harm. 11/18 AM (Pl.'s Opening) 31:15–24; 11/24 AM (Wilson) 73:22–74:1. It also admits that clinical trials are entered by obtaining an investigational device exemption (IDE) from the FDA. Yet FTC's own FDA expert agreed that IDE approval can take place within a matter of months. And because such submissions are non-public, a new entrant located abroad could already be under FDA review for an IDE to launch a feasibility study or pivotal trial, and therefore a matter of months—not years—away from catching up to the stage of FDA review where SOJOURN is today.

335. Overall, the FTC's novel theory would significantly expand Section 7 and chill life-saving innovation. The FTC has identified no case where any court has ever applied Section 7 to clinical trials.

II. The balance of equities and the public interest disfavor the requested injunction.

336. In addition to failing to establish a likelihood of success on the merits, the FTC has also failed to establish that its requested injunction is supported by the balance of equities or in the public interest. This, too, warrants denying the FTC's requested injunction.

337. These factors are particularly important in this case. This is not a merger of widget manufacturers where the combination will ultimately yield lower prices for consumers (although even that procompetitive benefit would be important). This is a merger of two heart-valve R&D streams whose combination provides the best chance to save thousands of lives. In every case, the FTC must show that its preliminary injunction is supported by the equities and in the public interest. But in this case, the FTC must do so with particular clarity because the consequences of getting it wrong are dire.

338. In determining whether to grant an injunction under Section 13(b), courts take a broad approach to assessing the equities and the public interest. For example, courts consider both public and private equities. *Weyerhaeuser*, 665 F.2d at 1082. And they consider the impact on the public interest at large, not just within the confines of the antitrust case brought by the government. *See id.*; *Tempur Sealy*, 768 F. Supp. 3d at 860–61.

339. As explained above, the merger will benefit the public. There are estimated to be over 100,000 Americans with severe symptomatic aortic regurgitation. PX-1078 at 50. Tens of thousands of those patients are either inoperable or at high risk for surgery. *Id.* And there is no FDA-approved TAVR-AR device today. Despite completing its pivotal trial over two years ago, JenaValve still does not have FDA approval and may never get it on its own. Instead, JenaValve received a deficiency letter from the FDA only two months ago. That will, at minimum, delay approval and renders approval of Trilogy uncertain. By contrast, as numerous witnesses—including the chairman of JenaValve's Board of Directors—testified, Edwards is best positioned

to resolve this issue and likely already could have but for the FTC's case. Even if JenaValve eventually manages to obtain FDA approval (far from certain), it lacks the expertise or resources to build the commercial TAVR-AR space. By contrast, Edwards is the leader in heart valves and TAVR, bringing decades of experience, robust manufacturing capabilities, and hundreds of millions of dollars in resources to the table.

340. The FTC's requested injunction will harm patients and prevent a merger that offers the best chance to save lives. Indeed, as witnesses testified, the FTC's investigation and case has *already* harmed JenaValve and its ability to get FDA approval. By contrast, the merger will likely expand access to life-saving treatment, benefiting the public interest. *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1302 (W.D. Mich. 1996) (denying FTC's requested preliminary injunction where hospital merger would improve ability of merged entity to save lives). "Because there is not yet an effective treatment . . . , any measure that accelerates the introduction of the first effective therapy, even by a matter of months, would save lives and reduce suffering." *Genzyme* at 6.

341. The requested injunction would also harm the private equities. Defendants have expended significant resources on the Transaction. They have held off closing for many months to give the FTC time to investigate and seek a preliminary injunction. And the merger agreement's termination date is January 23, 2026. Granting the preliminary injunction could kill the deal and irreparably injure Defendants. *See Tempur Sealy*, 768 F. Supp. 3d at 862 (relying on similar factors in denying preliminary injunction). And as discussed above, the delay and uncertainty around the deal has already harmed JenaValve, its employees' morale, and its ability to retain talent.

342. As with other parts of this case, the FTC asks the Court to blind itself to reality, insisting that courts do not consider the lost benefits of the merger in assessing the impact of a

requested injunction. 11/18 AM (Pl.'s Opening) 41:7–11. That is wrong. *E.g.*, Bench Op. 51:18–22, *FTC v. GTCR LLC*, No. 25-cv-2391 (N.D. Ill. Nov. 10, 2025) ("*GTCR*") ("The public equities are the interests of the public, either in having the merger go through or in preventing the merger. An analysis of the equities includes the potential benefits, both public and private, that may be lost by enjoining a merger."); *Tempur Sealy*, 768 F. Supp. 3d at 860–61 (considering benefits of merger that would be lost if enjoined); *Microsoft*, 681 F. Supp. 3d at 1100 (same); *Arch Coal*, 329 F. Supp. 2d at 160 (same); *see Penn State Hershey*, 838 F.3d at 352 (explaining that the public-interest inquiry boils down to this question: whether "harm . . . if the merger is delayed will, in turn, harm the public more than if the injunction is not issued").

343. The FTC's argument is also based on a false premise. The FTC pretends that there will be some administrative proceeding after the Court resolves the preliminary injunction, such that, at some future point many months later, the parties could revisit their merger. 11/18 AM (Pl.'s Opening) 41:7–19. "While expedient, that contention is entirely contrary to [the FTC's representations] made elsewhere," which acknowledge "that the decision as to preliminary injunction is—at least in the majority of circumstances—determinative of whether the acquisition will ever close." *Tempur Sealy*, 768 F. Supp. 3d at 861. As the FTC admitted in a recent merger litigation, the preliminary-injunction decision "almost always obviates the need for further . . . proceedings." *Id.* Or, as then-Commissioner Holyoak—joined by now-Chair Ferguson—put it: "when the FTC prevails in a preliminary injunction hearing, merging parties have proceeded with

the administrative hearing on only a few occasions because the proposed mergers almost always fall apart."[6]

344. The D.C. Circuit has recognized the same reality, holding that a preliminary injunction under Section 13(b) is "particularly" "extraordinary and drastic" because "the issuance of a preliminary injunction blocking an acquisition or merger may prevent the transaction from ever being consummated." *Exxon Corp.*, 636 F.2d at 1343. Other courts have noted the same, including as recently as last month, when a court rejected an FTC-requested injunction. *GTCR* at 53:7–13; *Microsoft*, 681 F. Supp. 3d at 1084–85; *Arch Coal*, 329 F. Supp. 2d at 160. Simply, the outside date is fast approaching and "[s]uch date is quite clearly a core term of the acquisition itself." *Tempur Sealy*, 768 F. Supp. 3d at 861. "Corporations have responsibilities to their shareholders, employees, and customers." *Id.* As discussed, uncertainty and delay in this Transaction has already hurt patients, shareholders, employees, and customers. And, considering "that the FTC nowhere places a deadline upon itself by which to conclude its inquiries," its "*just-close-later position*" cannot be taken seriously. *Id.*

345. The totality of the evidence shows that the Transaction will not harm competition or the public but will instead likely achieve a faster and better commercialization of a TAVR-AR device, enhancing innovation and competition, and potentially saving thousands of lives.

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Respectfully submitted,

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[6] Dissenting Statement of Comm'r Melissa Holyoak at 3, *In re Kroger Co.*, No. 9428 (FTC May 29, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/commn-holyoak-kroger-continuance-dissent-2024.05.29.pdf.

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