FTC Opening Statement

Federal Trade Commission v. Edwards Lifesciences, Corp., et al.

Case No. 1:25-cv-02569-RC

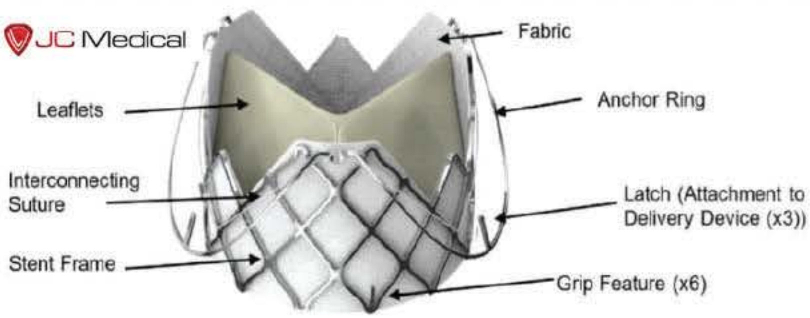
The Parties' Devices

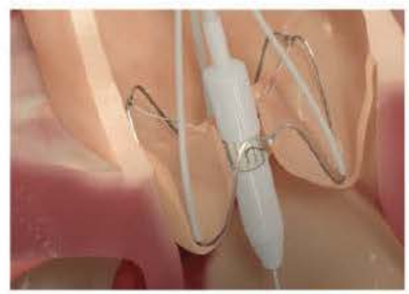
JenaValve Trilogy TAVR Device

Locator grasping of leaflets

Valve Deployment

J-Valve TAVR Device





U-shaped anchor rings positioned on the leaflets

Valve Deployment

PDX001-002

The Parties and Proposed Transaction

JC Medical

JENAVALVE

J-Valve/Sojourn

Trilogy

July 22, 2024

July 23, 2024

Edwards Lifesciences

PDX001-003

Competition for Premarket Approval

2024 At a Glance

JENAVALVE

AR Therapy
- AR continues to gain a high level of interest in the cardiology community
- New data + emerging clinical discussions support underdiagnosis/treatment w/ broad acceptance
- The 2024-25 is a critical juncture in our timeline to elevate AR further into the conversation

Trilogy
- JVT is considered the leader in the AR TAVR market segment
- Supported by the strength of our 1-YR pivotal data and the support of study investigators
- ALIGN CAP

Competition
- J-Valve is ga upcoming p
- J-Valve is ta
- Other AR-de

TAVR Market
- The bar for
- The US market is firmly split between EDW and MDT, as Navitor struggles and NEO2 faces delay.
- New devices must establish clear value/benefit to compete w/ market differentiators, including durability (SVD), coronary access, commissural alignment, pacemaker rate, ViV, and bicuspid.

"J-Valve is gaining momentum and poses a competitive threat with a newly completed EFS, an upcoming pivotal trial, and a credible roster of investigators."

PX2322 (JVT) at 005

Competition for Premarket Approval

[redacted]

PX1286 (EW) at 001

Competition for Clinical Trial Sites

Commercial Activity and Market Size:

- Due to our supply chain challenges, we have not as you know not been implanting in any material fashion
- Therapy awareness efforts however have been underway paving the groundwork for a high awareness impact in both the EU and US for 2023 and beyond
- CRT Meeting in DC – excellent clinical advisory board meeting – largely attended by our EU KOL
  - Continued strong support for Trilogy both AS and AR
- JValve (now owned by Genesis – former BSX leadership) is/was very aggressive literally chasing our investigators around the me… have selected s…
- They sh…
- We are… discussions and…

"JValve…is/was very aggressive literally chasing our investigators around the meeting hall."

PX2181 (JVT) at 002

Competition to Expand Size Offerings

To treat 105mm annulus (match J-valve) JVT needs 2 valves

J-Valve

	Annular Perimeter	
Valve	Min	Max
22	57	66
25	66	75
28	75	85
31	85	94
34	94	104

Trilogy

	Annular Perimeter	
Valve	Min	Max
N/A	N/A	N/A
23	66	76
25	76	83
27	83	90
29	90	97
31	97	105

To match J-valve offering , JVT needs to large valve size

PX2190 (JVT) at 009

Competition to Treat Lower-Risk Patients

From: Ryan Polzin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D8982AE6C46F4BBAA07042E2E219B43A-RYAN POLZIN]
Sent: 2/8/2024 4:43:16 PM
To: Daniel Sun [dsun@jenavalve.com]; Peter Spadaro [spadaro@jenavalve.com]; Duane Pinto, MD, MPH [pinto@jenavalve.com]; John Kilcoyne [kilcoyne@jenavalve.com]
Subject: Re: J-Valve

Thanks Daniel. If that's how it pans out, m
stay ahead of them.

Let's go baby! Bring it on!

Best Regards,
Ryan

Ryan Polzin
Director of Strategy and Field Operations

JENAVALVE

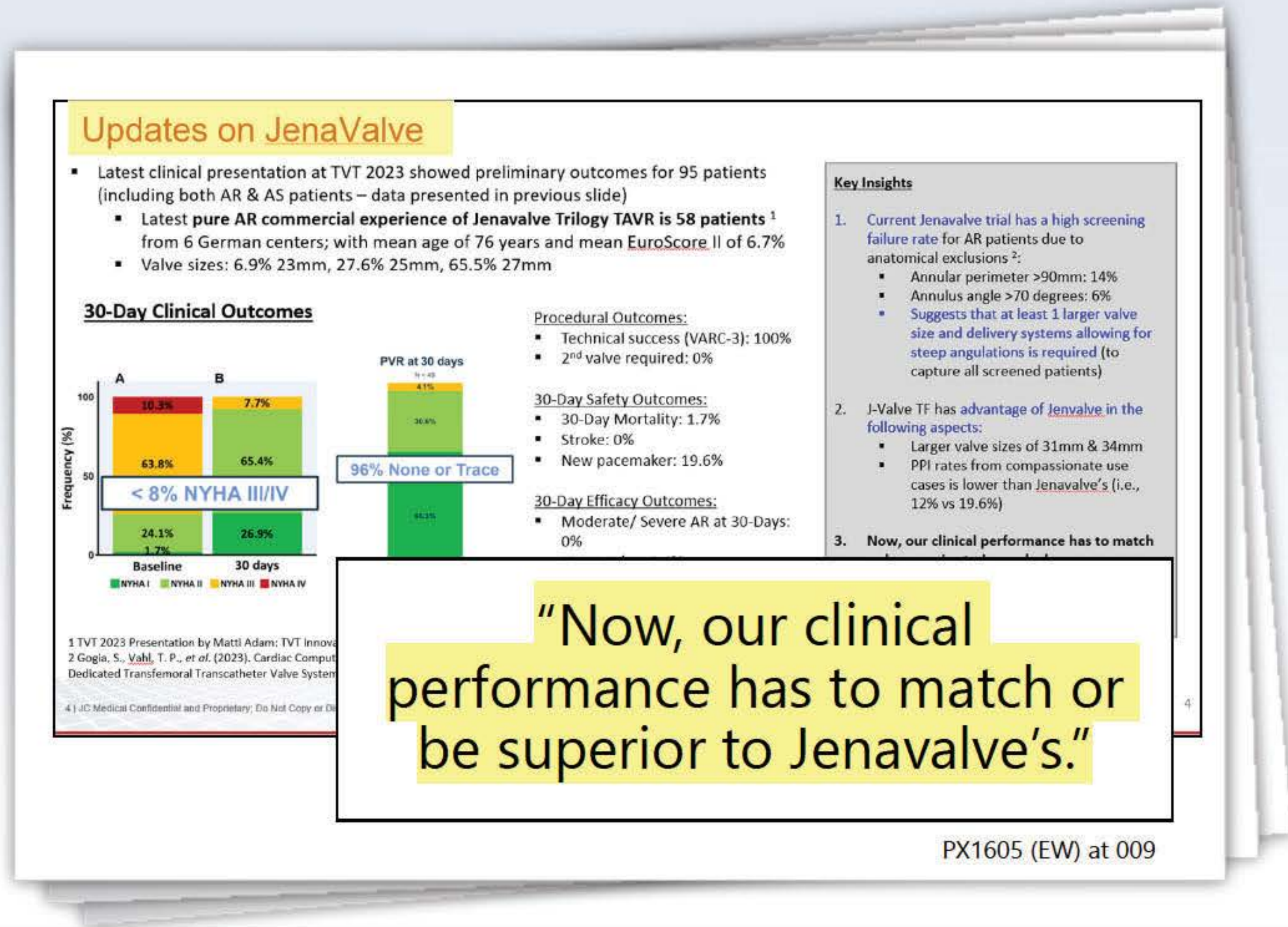
PX2042 (JVT) at 001

"moving fast on the next trial for Trilogy will be of huge strategy importance to stay ahead of [J-Valve]."

"Let's go baby! Bring it on!"

PDX001-008

Competition for Best Clinical Data



Updates on JenaValve

- Latest clinical presentation at TVT 2023 showed preliminary outcomes for 95 patients (including both AR & AS patients – data presented in previous slide)
  - Latest **pure AR commercial experience of Jenavalve Trilogy TAVR is 58 patients** [1] from 6 German centers; with mean age of 76 years and mean EuroScore II of 6.7%
  - Valve sizes: 6.9% 23mm, 27.6% 25mm, 65.5% 27mm

30-Day Clinical Outcomes

Procedural Outcomes:
- Technical success (VARC-3): 100%
- 2nd valve required: 0%

30-Day Safety Outcomes:
- 30-Day Mortality: 1.7%
- Stroke: 0%
- New pacemaker: 19.6%

30-Day Efficacy Outcomes:
- Moderate/ Severe AR at 30-Days: 0%

Key Insights

1. Current Jenavalve trial has a high screening failure rate for AR patients due to anatomical exclusions [2]:
   - Annular perimeter >90mm: 14%
   - Annulus angle >70 degrees: 6%
   - Suggests that at least 1 larger valve size and delivery systems allowing for steep angulations is required (to capture all screened patients)
2. J-Valve TF has advantage of Jenvalve in the following aspects:
   - Larger valve sizes of 31mm & 34mm
   - PPI rates from compassionate use cases is lower than Jenavalve's (i.e., 12% vs 19.6%)
3. **Now, our clinical performance has to match**

1 TVT 2023 Presentation by Matti Adam: TVT Innova
2 Gogia, S., Vahl, T. P., *et al.* (2023). Cardiac Comput
Dedicated Transfemoral Transcatheter Valve System

4 | JC Medical Confidential and Proprietary; Do Not Copy or Di

4

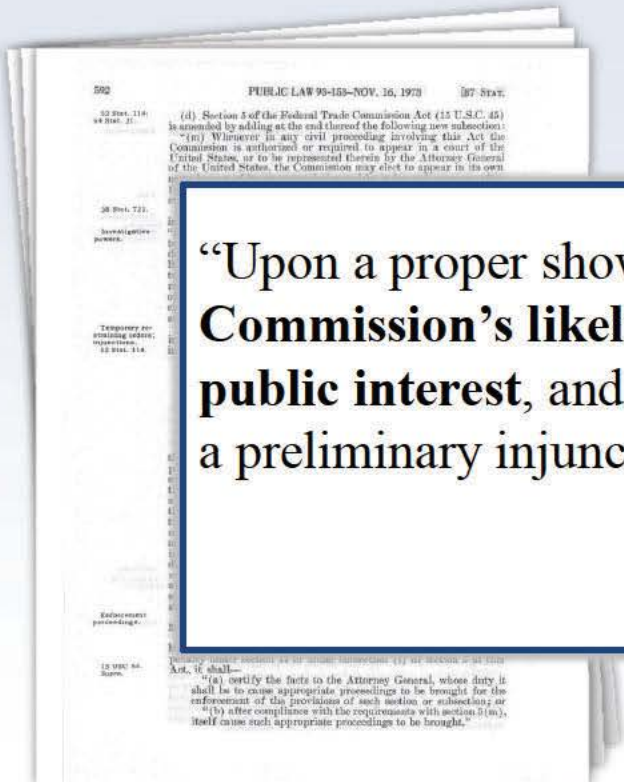
"Now, our clinical performance has to match or be superior to Jenavalve's."

PX1605 (EW) at 009

Roadmap

1. Introduction
2. Legal Standard
3. Background
4. Market Definition
5. Prima Facie Case
6. Defendants Cannot Meet Their Burden
7. Competitive Effects
8. Equities

Statutory Standard for Preliminary Injunction


592 PUBLIC LAW 93-153–NOV. 16, 1973 [87 STAT.

(d) Section 5 of the Federal Trade Commission Act (15 U.S.C. 45) is amended by adding at the end thereof the following new subsection:
"(m) Whenever in any civil proceeding involving this Act the Commission is authorized or required to appear in a court of the United States, or to be represented therein by the Attorney General of the United States, the Commission may elect to appear in its own

Act, it shall—
"(a) certify the facts to the Attorney General, whose duty it shall be to cause appropriate proceedings to be brought for the enforcement of the provisions of such section or subsection; or
"(b) after compliance with the requirements with section 5(m), itself cause such appropriate proceedings to be brought."

"Upon a proper showing that, **weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest**, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be ordered without bond."

Federal Trade Commission Act § 13(b), 15 U.S.C. § 53(b)

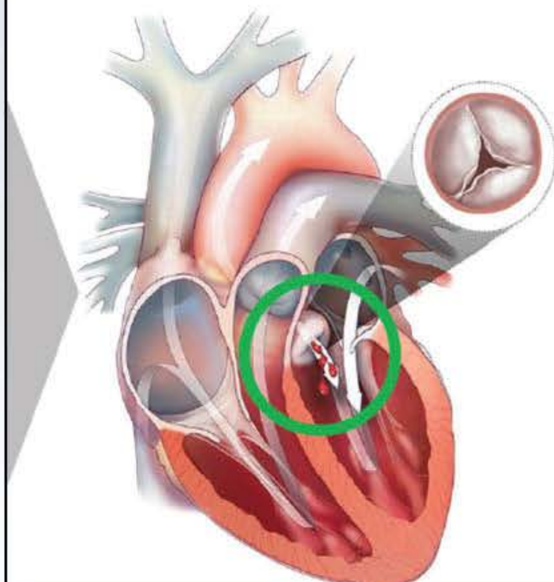
PDX001-011

Roadmap

1. Introduction
2. Legal Standard
3. Background
4. Market Definition
5. Prima Facie Case
6. Defendants Cannot Meet Their Burden
7. Competitive Effects
8. Equities

Aortic Regurgitation

Aortic Regurgitation ("ssAR")



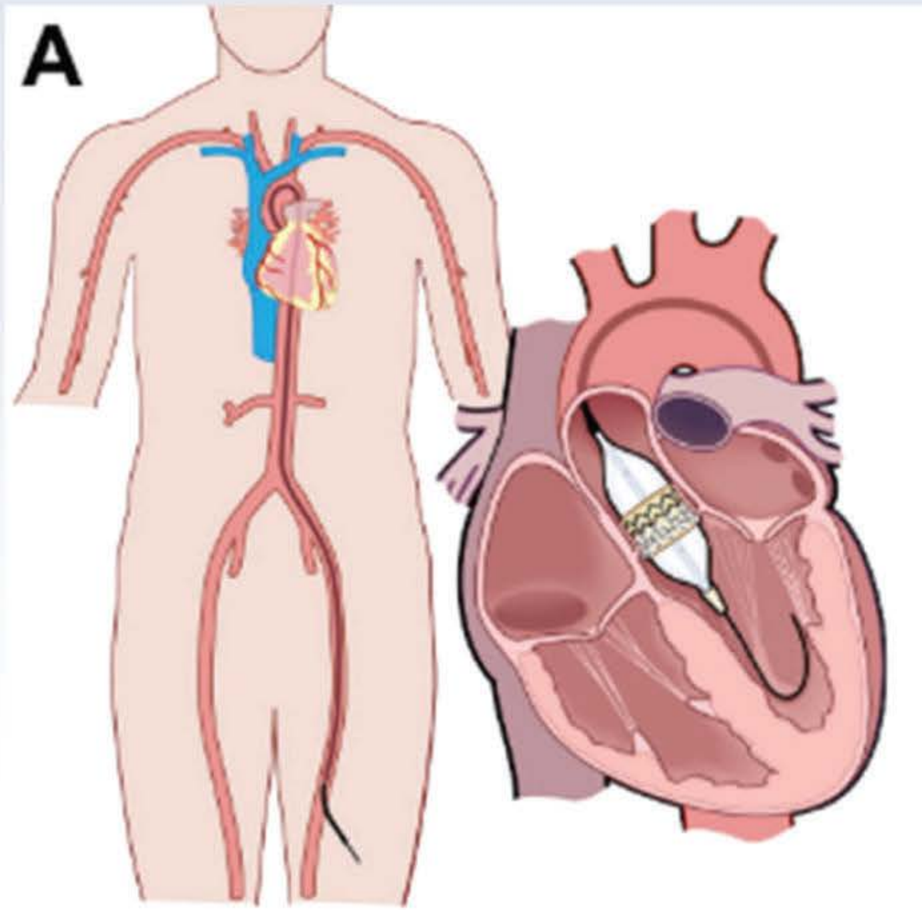
A Regurgitant Aortic Valve Fails to Close, Allowing Blood to Leak Backwards

NOT Amenable to Existing TAVR's Use of Radial Force to Anchor

- No Stenosis of the Valve
- No Calcification of Leaflets/Annulus
- Compliant anatomy

PX2327 (JVT) at 005

TAVR: Transcatheter Aortic Valve Replacement



PDX001-014

FTC Expert: Dr. Aaron Kesselheim

Penn Carey Law
UNIVERSITY of PENNSYLVANIA

Perelman
School of Medicine
UNIVERSITY of PENNSYLVANIA

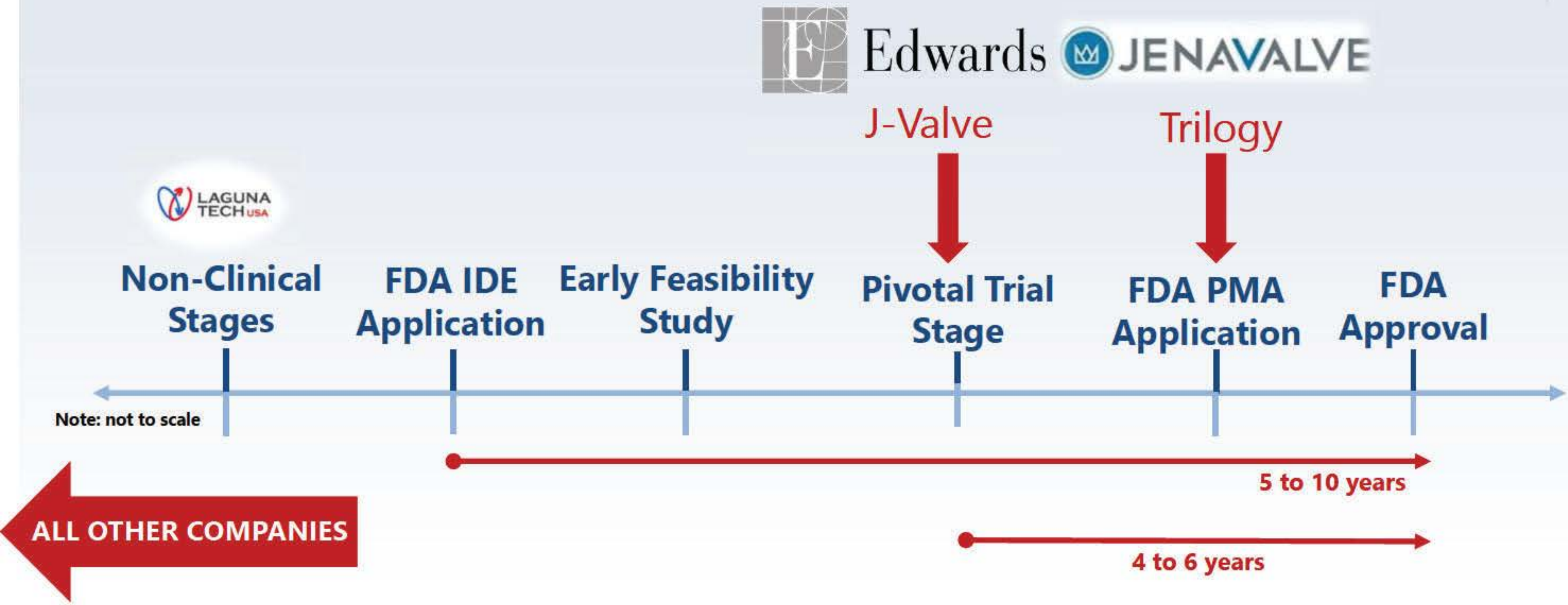
HARVARD
T.H. CHAN
SCHOOL OF PUBLIC HEALTH

Yale Law School

BRIGHAM
AND
WOMEN'S
HOSPITAL

NATIONAL
ACADEMY
of MEDICINE

Edwards and JenaValve: Only Two Companies in US Clinical Trials



PDX001-016

Roadmap

1. Introduction
2. Legal Standard
3. Background
4. Market Definition
5. Prima Facie Case
6. Defendants Cannot Meet Their Burden
7. Competitive Effects
8. Equities

Geographic Market

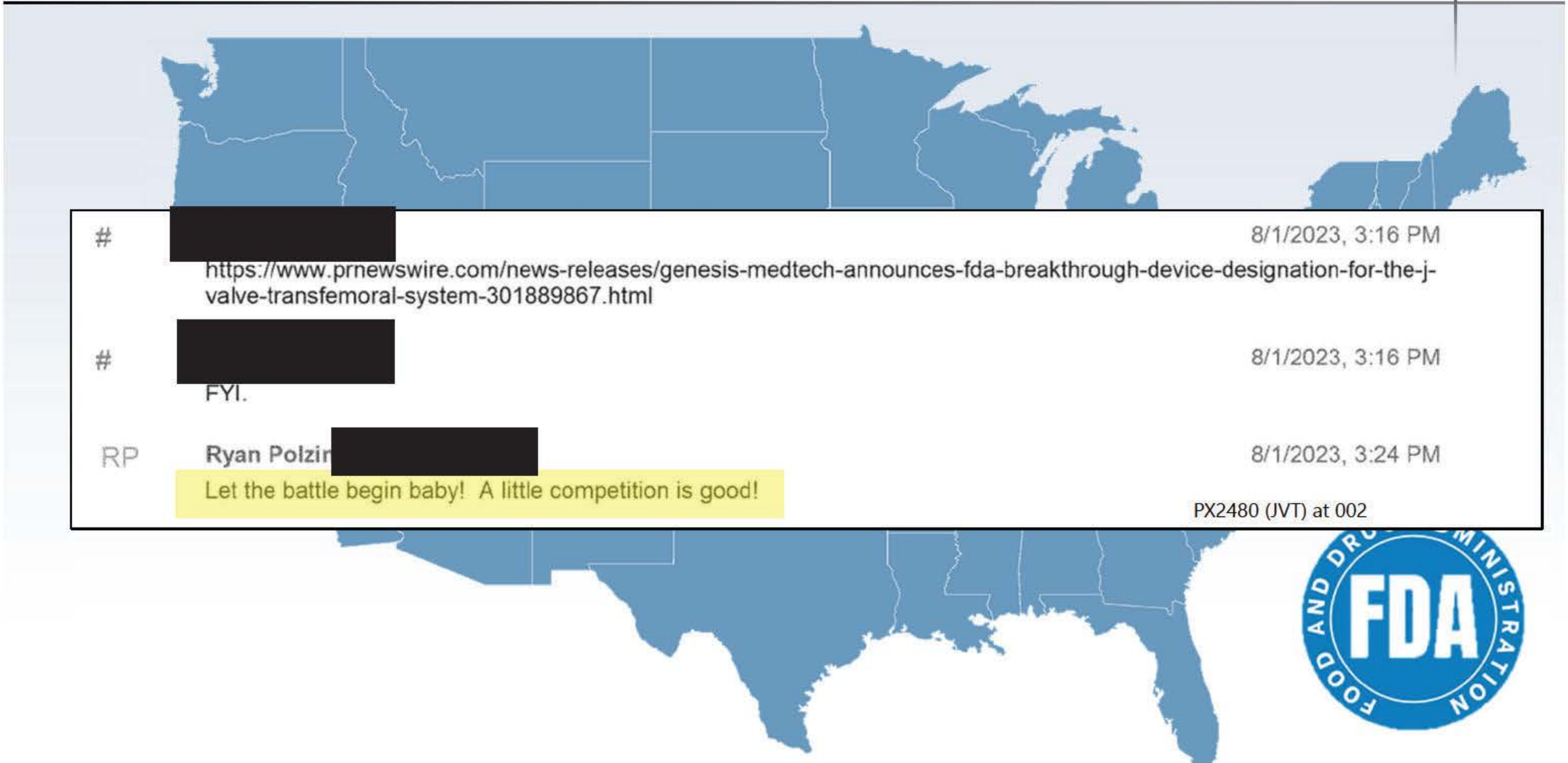
"For Clayton Act purposes, the Supreme Court has defined the relevant geographic market as the region 'in which the seller operates, and to which the purchaser can practicably turn for supplies.'"

FTC v. Cardinal Health, Inc., 12 F.Supp.2d 34, 49 (D.D.C. 1998)

"[T]he area of effective competition . . . must be charted by careful selection of the market area in which the seller operates, and to which the purchaser can practicably turn for supplies."

Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 327 (1961)

The Geographic Market is the United States



#	[redacted] https://www.prnewswire.com/news-releases/genesis-medtech-announces-fda-breakthrough-device-designation-for-the-j-valve-transfemoral-system-301889867.html	8/1/2023, 3:16 PM
#	[redacted] FYI.	8/1/2023, 3:16 PM
RP	**Ryan Polzi**[redacted] Let the battle begin baby! A little competition is good!	8/1/2023, 3:24 PM

PX2480 (JVT) at 002

PDX001-019

Defendants View United States as a Distinct Market

Message

From: Blessie Concep
(FYDIBOHF23SP
Sent: 8/1/2024 1:02:
To: Jaime Wheeler
Prince [Heathe
Subject: RE: AR London Mtg 31-Jul-2024

Updates on JenaValve – Our closest competitor in USA TAVR (AR) Market

PX1037 (EW) at 016

Please disregard prior email and refer to the updated version below.

a. Proceed with JOURNEY AR HR Pivotal trial: review protocol to ensure there are no major issues [redacted] device manufactured in China can be used in trial (need to improve anchor ring attachment during prep and detachment during procedure without dislodging valve) but cannot be used to commercialize in the US – need to transfer manufacturing from China to Canada or in-house

# of sites (focus on US only), device manufactured i [redacted]
during prep and detachment during procedure witho
need to transfer manufacturing from China to Canad

PX1280 (EW) at 001

PX2461 (JVT) at 003

PDX001-020

Product Market Defined by Substitutability

"The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it."

Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)

"[C]ourts look at 'whether two products can be used for the same purpose, and, if so, whether and to what extent purchasers are willing to substitute one for the other.'"

United States v. H&R Block, Inc., 833 F.Supp.2d 36, 51 (D.D.C. 2011)

PDX001-021

Competition Defines Antitrust Markets

"Thus, the relevant market is defined as 'the area of effective competition.'"

Ohio v. Am. Express Co., 585 U.S. 529, 543 (2018)

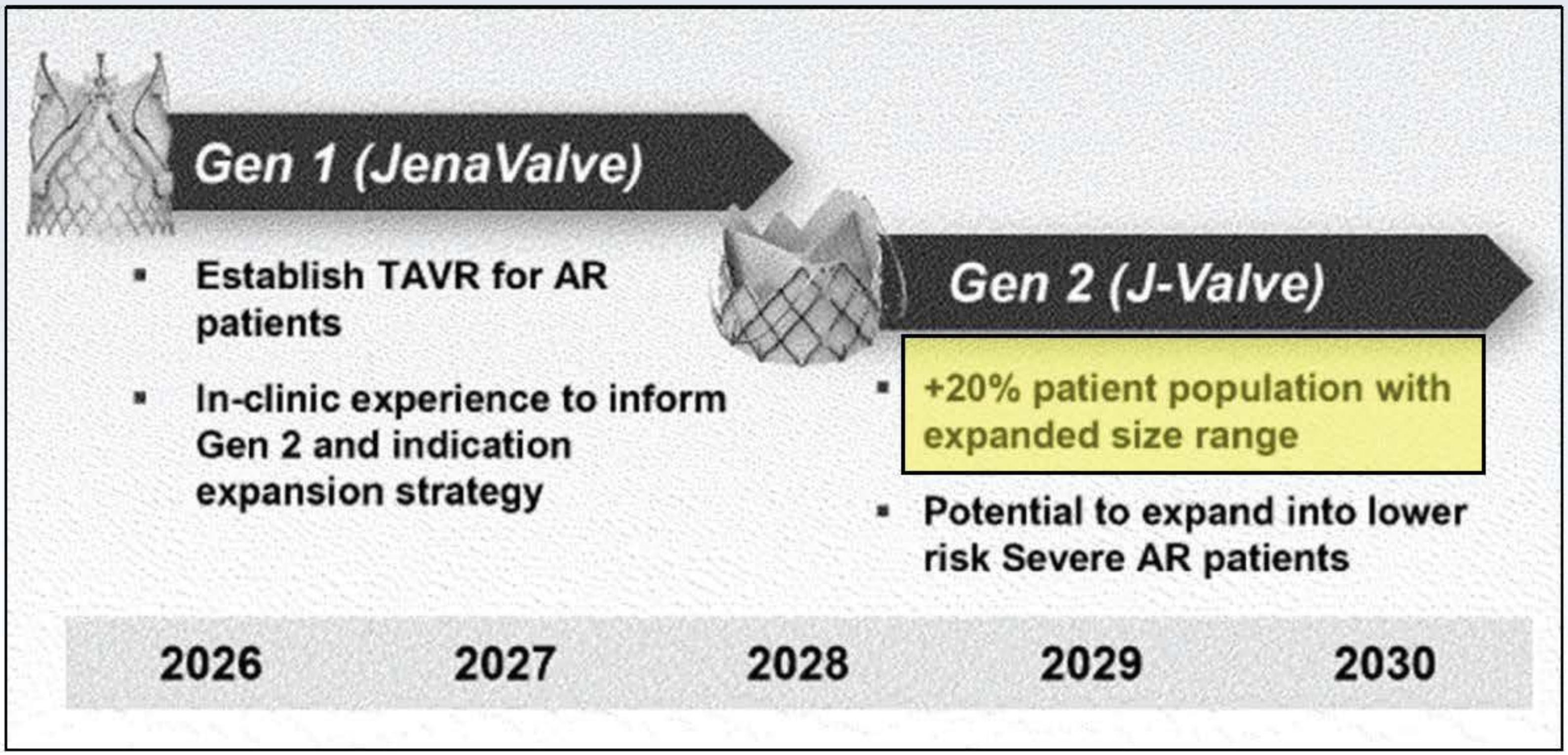
Defining Product Market: *Brown Shoe* Practical Indicia

- the product's peculiar characteristics and uses
- distinct customers
- distinct prices
- industry or public recognition of the market
- ordinary course documents' portrayal of market realities

Brown Shoe, 370 U.S. 294, 325 (1962)

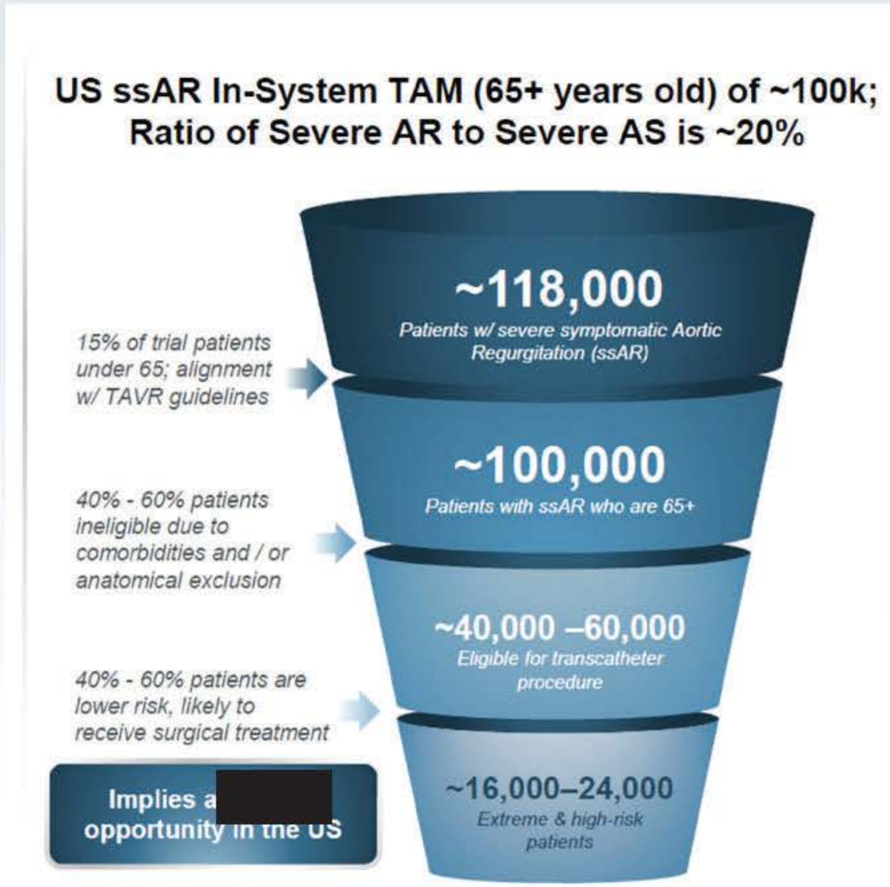
PDX001-023

Brown Shoe: Peculiar Characteristics and Uses



PX1394 (EW) at 003

Brown Shoe: Distinct Customers



PX1078 (EW) at 050

Brown Shoe: Distinct Prices

Project Jupiter
P2 Diligence Readout

June 28, 2024

Edwards Lifesciences

Diligence Leaders:
Pooja / Jeremy / Meredith / Martyn

[redacted]

Commercial Diligence Summary

Categories	Effort Req.	Key Issues/Findings
Market Opportunity	[redacted]	No issu[redacted] opportunity with planned ssAR ≥High-risk indication
Differentiation		**Strengths**: First to market in US; approved in Europe; anchoring mechanism for [redacted] leaflets; stable deployment & positioning; positive clinical outcomes (mortality, str[redacted] embolism, AR < moderate) **Weaknesses**: Limited upper end of valve sizing (≤28.6mm diameter / 85mm peri[redacted] screen out rate in ALIGN-AR: valve is oversized to annulus; learning curve to ach[redacted]
KOLs		
Traini[ng] Proce[ss]		
Global Launch Strategy	[redacted]	

[redacted] list ASP [redacted] net ASP)"

- **Opportunities**: Establish TAVR therapy for AR in the US with target premium pricing for dedicated AR TAVR product: [redacted] list ASP [redacted] et ASP). ALIGN-AR 2-year data planned for TCT 2024; CT analysis & RWE at LV 2024. eg[redacted] project being formulated.

PX1453 (EW) at 007, 009

Project Dragon
Diligence Readout

June 28, 2024

Edwards Lifesciences

Diligence Leaders:
Pooja / Jeremy / Meredith / Martyn

[redacted]

Commercial Diligence Summary

Categories	[redacted]	Key Issues/Findings
Market Opportunity	[redacted]	No issu[redacted] planned ssAR ≥High-risk indication
Differentiation		**Strengths**: Interest in device from compassionate-use & EFS experience; ability to treat **larger annulus patients** (labeled up to ≤33mm diameter / ≤104mm perimeter); ability to track horizontal aort[ic] (aortic annulus angle >80° excluded in EFS); anchoring mechanism for non-calcified leaflets; stable deployment & positioning; positive initial clinical outcomes (mortality, stroke, valve embolism, AR <
KO[Ls] Ad[...]		
Tr[aining] Pr[ocess] Su[...]		
Global Launch Strategy	[redacted]	[redacted]

[redacted] list ASP [redacted] net ASP)"

Opportunities: US market is the priority to establish with target premium pricing for dedicated AR TAVR product[redacted] st ASP [redacted] et ASP); IDE experience will inform US commercial launch strategy; Europe strategy TBD but can[redacted] pan strategy TBD

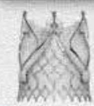
PX1453 (EW) at 003, 005

Brown Shoe: Industry Recognition

LIVE

Acquisition of Both Dedicated AR Technologies Enables Edwards to Lead the Therapy and Deliver a Strong Value Proposition to Patients

Speed to Market



Project Jupiter (Trilogy)

Value Proposition:
- 1st dedicated AR product in US market (target Q4 2025)
- Compelling clinical evidence
- Large open cells for future coronary access

Clinical Experience:
- ALIGN-AR pivotal IDE: N=180, 1-year follow-up, 20 US sites
- Approx[redacted]otal patients in PMA, CAP, and AS

Potential for Long-Term Differentiation

Project Dragon (J-Valve)

Value Proposition:
- 5 sizes to treat larger annuli
- Bovine pericardium
- Low profile frame for future coronary access

Clinical Experience:
- EFS: N=15, 30-day follow-up, 5 [redacted]
- Compassionate use experience [redacted] 30-day follow-up, 3 US & 2 Canada sites

Abbreviations: AR = aortic regurgitation; AS = aortic stenosis; CAP = continued access plan; EFS = early feasibility study; PMA = pre-market approval

CONFIDENTIAL

PX1530 (EW) at 014

DB	Devin Baerenwal[redacted]	What's the vibe in house? Sounded like a lot of fear from the audience.	7/24/2024, 11:33 PM
DS	Daniel Sun [redacted]	Dude it's like a funeral	7/24/2024, 11:33 PM
DS	Daniel Sun [redacted]	So freaking weird	7/24/2024, 11:33 PM
DB	Devin Baerenwald [redacted]	😂	7/24/2024, 11:36 PM
DB	Devin Baerenwald [redacted]	How are you feeling?	7/24/2024, 11:36 PM
DS	Daniel Sun <	I'm worried ou	
DB	Devin Baeren	Yeah, I'm pret	
DB	Devin Baeren	Chris got forw … Medical, which I haven't seen anywhere online, but that would mean Edwards just bought the AR market.	
DS	Daniel Sun [redacted]	It's not right	7/24/2024, 11:44 PM

"...that would mean Edwards just bought the AR market."

PX2052 (JVT) at 002

PDX001-027

Parties' Ordinary Course Documents Given Significant Weight

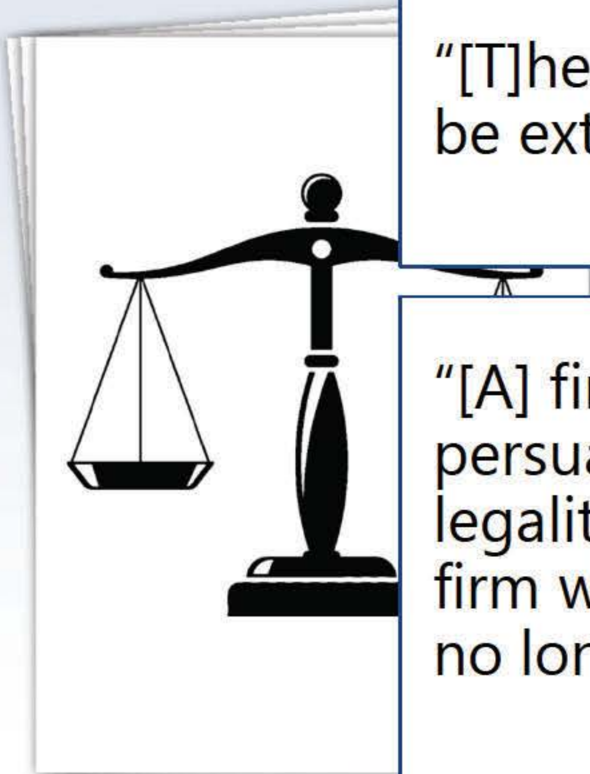
"Courts frequently rely on ordinary course documents and witness testimony illustrating that two merging parties view each other as strong competitors."

FTC v. IQVIA Holdings Inc., 710 F.Supp.3d 329, 383 (S.D.N.Y. 2024)

"When determining the relevant product market, courts often pay close attention to the defendants' ordinary course of business documents."

United States v. H&R Block, Inc., 833 F.Supp.2d 36, 52 (D.D.C. 2011)

Documents Created During Regulatory and Litigation Processes



"[T]he probative value of such evidence was found to be extremely limited . . . ."

United States v. General Dynamics Corp., 415 U.S. 486, 504 (1974)

"[A] firm's behavior undertaken with the aim of persuading a court or the government regarding the legality of a merger may not be predictive of how that firm will behave once the court or the government are no longer engaged."

United States v. Aetna Inc., 240 F.Supp.3d 1, 80 (D.D.C. 2017)

Sanitized Documents

PX1453 (EW) at 001

Hi Pooja and Jeremy,

"I've been given guidance to share strengths vs weaknesses instead of H2H comparison"

Meredith Zia
Portfolio Strategy
Transcatheter Heart Valves
Edwards Lifesciences

PX2465 (JVT) at 002

iyake@jenavalve.com) 8/6/2025, 5:46 PM

nesswire.com/news/home/20250806182521/en/Edwards-Lifesciences-Comments-on-FTCs-Action-to-Acquisition-of-JenaValve

"Not appropriate to discuss here or in any medium"

"FYI moving forward, let's don't write anything about JV down, as it can get subpoenaed ☺ nothing juicy in your notes"

PX1300 (EW) at 001

nathan_Ong@edwards.com>; Jonathan Lee

Subject: Re: JC Medical for THV Strat 2025

Thanks Ken!

FYI moving forward, let's don't write anything about JV down, as it can get subpoenaed ☺ nothing juicy in your notes, just a good practice

Sent: Friday, May 23, 2025 4:57 PM

To: Scott Ullem <Scott_Ullem@edwards.com>; Mark Wilterding <Mark_Wilterding@edwards.com>

"AR was handled carefully this submission due to the FTC review."

accordingly. AR was handled carefully this submission due to the FTC review. The TAVR team was abl

holistic topline based on market model assumptions for AR – meaning the revenue you see assumes

AR product in 2026. From a spend standpoint, the TAVR team only submitted expenses for JC Medica

$40M. Behind the scenes and not visible on that ELT target reconciliation schedule, our team submitt

PX1537 (EW) at 001

"You know, the only thing I can say is at some point we got into the habit that documents that contained items in the transaction, that we copied lawyers on those."

Keltjens (JVT) Dep. 134:3-9

FTC Expert: Dr. Nathan Wilson

<u>**Conclusion:**</u> The proposed transaction is likely to substantially lessen competition

- The relevant market is the supply of TAVR-AR devices to American consumers
- The proposed transaction would dramatically increase concentration
- **The loss of competition between JenaValve and Edwards would likely harm consumers**

Hypothetical Monopolist Test

"In the merger context, this inquiry boils down to whether 'a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products ... likely would impose at least a small but significant and non-transitory increase in price ('SSNIP') on ... at least one product sold by one of the merging firms.'"

United States v. H&R Block, 833 F.Supp.2d 36, 52 (D.D.C. 2011) (quoting the 2010 Horizontal Merger Guidelines § 4.1.1.)

Roadmap

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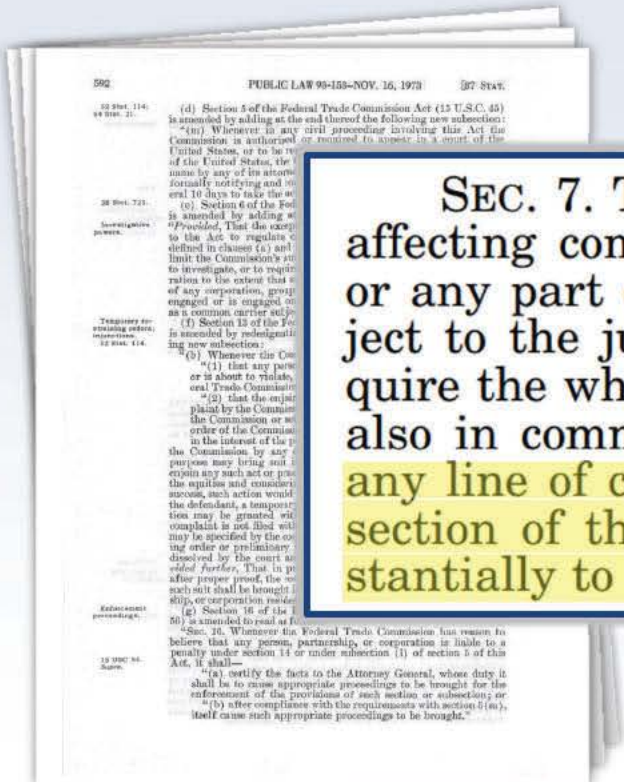
Section 7 of the Clayton Act (15 U.S.C. § 18)



SEC. 7. That no person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

Proposed Transaction Tends to Create a Monopoly

"Thus, plaintiff's showing of the creation of a 100 percent monopoly for the bid on the 1994-98 contract and the barrier to future entry alone suggest a *per se* violation of the Clayton Act justifying a plaintiff's preliminary relief."

FTC v. Alliant Techsystems, Inc., 808 F. Supp. 9, 21 (D.D.C. 1992)

"'[T]he anticompetitive effect of the merger is further enhanced by high barriers to market entry. . . . As far as we can determine, no court has ever approved a merger to duopoly under similar circumstances."

FTC v. H.J. Heinz Co., 246 F.3d 708, 717 (D.C. Cir. 2001)

Proposed Transaction is Presumptively Illegal Based on Market Share and HHIs

" Without attempting to specify the smallest market share which would still be considered to threaten undue concentration, we are clear that 30% presents that threat. . . . [and] this increase of more than 33% in concentration must be regarded as significant."

U.S. v. Philadelphia Nat'l Bank, 374 U.S. 321, 364 (1963)

" Dr. Nevo further explained at the evidentiary hearing and in his reply report that he performed multiple alternative HHI calculations using several of Defendant's preferred candidate markets. . . . The results in each case satisfied the Guidelines threshold for a structural presumption. . . . In sum, the court finds that based on Dr. Nevo's testimony and other evidence, the FTC has demonstrated that the proposed merger will significantly increase concentration in the market[.]"

FTC v. Wilh. Wilhelmsen Holding ASA, 341 F.Supp.3d 27, 62 (D.D.C. 2018)

From Two Devices to Only One

Sean Kim [redacted] ▶ 7/25/2024, 3:30 PM
I don't buy this shit at all. EW is going to only keep one or the other. JC acquisition is a threat to us

Daniel Sun [redacted] 30 PM
Yes

Daniel Sun [redacted] 30 PM
That's what I'm saying. They will see which one is better and kill the other

“I don’t buy this shit at all. EW is going to only keep one or the other. JC acquisition is a threat to us”

PX2062 at 002

PDX001-037

The Proposed Transaction Eliminates Substantial Competition

"[B]ecause the proposed merger would eliminate head-to-head competition between the number one and number two competitors in the market . . . , the merger is likely to lead to unilateral anticompetitive effects in that market. Evidence of probable unilateral effects strengthens the FTC's prima facie case that the merger will lessen competition . . . ."

FTC v. Sysco Corp., 113 F. Supp. 3d 1, 65 (D.D.C. 2015)

Proposed Transaction Eliminates Substantial Competition

- J-VALVE: J-Valve is moving forward with JOURNEY and will begin cases soon. They are in many ALIGN-AR sites and will benefit from the awareness programs and referral pathways we have forged. Strategically, I think we should launch ARTIST and commercialize at all JOURNEY sites and get creative in an effort to get them to prioritize Trilogy implants over J-Valve. (Stack cases, consider pricing rebates, etc.)

PX2414 (JVT) at 002

Dr. Kereiakes
The Christ Hospital

Q And I believe you said that previously
JC Medical J-Valve devices had been given to

Page 51

The Christ Hospital for free, right?
A Yes.

Kereiakes (Christ Hospital) Dep. 50:24-51:2

Proposed Transaction Eliminates Substantial Competition

As to business plan 2024, I am would like to suggest following approach:

- Run the ARTIST IDE study asap. We need this to stay ahead of competitors and keep investigators engaged. The incremental cash cost (net of proceeds from selling devices to centers) should be relatively small (sub $1M, however this assumes starting a number of sites at cost of $8M and enrolling 240 patients).

PX2381 (JVT) at 001

JENAVALVE

Why ARTIST Now?

- J-Valve to Start "Journey" ssAR High Risk IDE in 2H '24
- Prevent J-Valve overtaking JVT High Ground
- Prevents Loss of JVT credibility customers/accts
- Along w/ CAP - Slows J-Valve Enrollment
- Blocks J-Valve From JVT Site Penetration
- Enables JVT to Maintain Podium Cadence
- Provides Soft Aircover fo [redacted]
- Sets Stage Fo [redacted]
- Value Add to Strategics

PX2186 (JVT) at 023

JENAVALVE

Why Large Valve Now?

- Competitor J-Valve Already Has a Large Valve Size In Portfolio
- Prevents Loss of Customers Who Only Want **One** AR Valve Manufacturer
- Blocks J-Valve From JVT Site Penetration

[redacted]

- Value Add to Strategics

PX2186 (JVT) at 024

Roadmap

1. Introduction
2. Legal Standard
3. Background
4. Market Definition
5. Prima Facie Case
6. Defendants Cannot Meet Their Burden
7. Competitive Effects
8. Equities

Congress Has Decided in Favor of Competition

"[A] merger the effect of which 'may be substantially to lessen competition' is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial. A value choice of such magnitude is beyond the ordinary limits of judicial competence, and in any event has been made for us already, by Congress..."

United States v. Phila. Nat'l Bank, 374 U.S. 321, 371 (1963)

"[U]ntil Congress says otherwise, the only law it has asked us to enforce is the Sherman Act, and that law is predicated on one assumption alone — 'competition is the best method of allocating resources' in the Nation's economy."

NCAA v. Alston, 594 U.S. 69, 96 (2021)

PDX001-042

Courts Apply the *Baker Hughes* Burden-Shifting Framework

1. FTC's Initial Burden

- Prima facie case that merger violates the Clayton Act

2. Burden Shifts to Defendants

- Must present evidence to rebut FTC's prima facie case

3. FTC's Ultimate Burden

- If sufficient rebuttal, produce additional evidence of anticompetitive effects
- Burden merges with the ultimate burden of persuasion

PDX001-043

Defendants Cannot Prove that Timely, Sufficient Entry is Likely

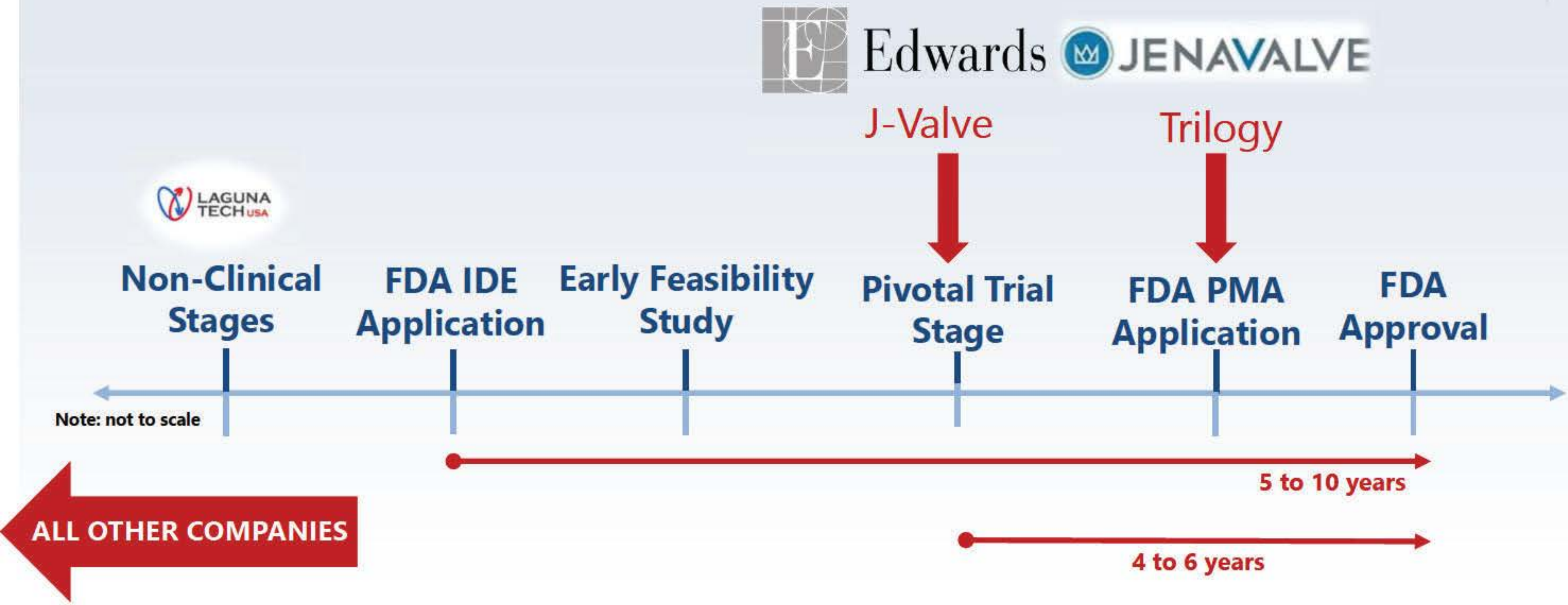
"Entry or expansion into a relevant market must be 'timely, likely, and sufficient in its magnitude, character, and scope' to counteract a merger's anticompetitive effects."

United States v. Anthem, Inc., 236 F. Supp. 3d 171, 222 (D.D.C. 2017)

"The relevant time frame for consideration in this forward looking exercise is two to three years."

FTC v. Staples, 190 F. Supp. 3d 100, 133 (2016)

Edwards and JenaValve: Only Two Companies in US Clinical Trials



JC Medical Market Projections – 100% of US TAVR-AR thru 2035

[redacted]

PX1065 (EW) at Excel ending -930)

PDX001-046

Edwards' View on Chinese Companies

Bernard Zovighian
CEO, Edwards

Message

From: Bernard Zovighian [Bernard_Zovighian@edwards.com]
Sent: 5/1/2024 12:18:20 PM
To: Larry Wood [Larry_Wood@edwards.com]; Jean-Luc Lemercier [Jean-Luc_Lemercier@edwards.com]; Dan Lippis [Dan_Lippis@edwards.com]; Scott Ullem [Scott_Ullem@edwards.com]; Arnold Pinkston [Arnold_Pinkston@edwards.com]
Subject: RE: Competitive Intel Update: MicroPort Receives CE Mark Approval for VitaFlow Liberty

I am wondering if this company will be part of the EU probe initiated by the EU commission since Data seems to have been generated in China and manufacturing is in China.
At next ELT, can we finalize a decision about what we should do about these type of technologies (lack of rigorous evidence, manufacturing in China or India, ...). They put the patients at risks and therefore could impact negatively the

"At next ELT, can we finalize a decision about what we should do about these type of technologies (lack of rigorous evidence, manufacturing in China or India, ...). **They put the patients at risks and therefore could impact negatively the TAVR field**."

PX1120 (EW) at 001

Don Bobo Jr.
CVP, Edwards

"China has been **highly criticized** for providing fraudulent data to the FDA and making up test data and not actually delivering and manufacturing what they said."

eggshells very concerned that we'd find a lot of that.

Bobo (EW) Dep. 198:7-199:1

PDX001-047

Defendants' Speculative Efficiencies Are No Defense

"Possible economies cannot be used as a defense to illegality. Congress was aware that some mergers which lessen competition may also result in economics, but it struck the balance in favor of protecting competition."

FTC v. Procter & Gamble, 386 U.S. 568, 580 (1967)

Edwards Chose Not to Attempt Verification

John Kilcoyne
CEO, JenaValve

Q. Could that involve competitively sensitive information?
A. It's possible.
Q. Is there a clean team in place for the proposed acquisition of JenaValve by Edwards?
A. Yes.
Q. Okay. I'd like to introduce a document

Kilcoyne (JVT) Dep. 9:19-21

Don Bobo Jr.
CVP, Edwards

BY MS. HALL:
Q Are you familiar with the use of a clean room process to facilitate evaluation of confidential information prior to the occurrence of an acquisition?
A Just so I'm clear -- I want to make sure I understand your question. We call it a clean team. So it's not just a room that's clean. It's actually people that you separate and say you're able to look at this in exchange for the next two to three to four years, whatever you negotiate, you're unable to ever work in this field.
So yes, I am familiar with that, and we use that from time to time where -- where the details and the specifics of the case make sense. So I am familiar with that construct.

Bobo (EW) Dep. 21:15-22:3

PDX001-049

Evidence of Hostility is Relevant to Efficiencies Claims

MEMORANDUM OPINION

GRANTING PLAINTIFF'S MOTION TO COMPEL DISCOVERY RESPONSES FROM DEFENDANT JENAVALVE TECHNOLOGY, INC.

[redacted]

ECF No. 78 at 006

John Kilcoyne
CEO, JenaValve

PX2282 (JVT) at 002

Thanks – very helpful
Would you have time for a 30mi
We have a real flight risk situati
have read it...
There is a strong and growing se
1. the deal will not be appr
2. thus, we will not close a
3. I have waited a year – w
4. Based upon what I read in the FTC report – I don't trust EW and don't think I would want to work there anyway

"I don't trust EW and don't think I would want to work there anyway"

Comparison: JVT and EW Projections of Device Sales

[redacted]

FTC and JenaValve Propose Divesting JC Medical

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Bureau of Competition

August 6, 2025

D. Bruce Hoffman, Esq.

"In our view, it is not too late to pursue a divestiture of JC Medical."

for Edwards came in person to meet with Staff on December 18, 2024. Staff reiterated that a divestiture would likely resolve the investigation. As the investigation progressed through the first half of 2025, Staff continued to ask Edwards in status updates if its stance on a divestiture had changed. We raised the possibility of a JC Medical divestiture again in our Bureau of Competition Front Office meeting on July 24, 2025, as well as when you met with the Chairman on July 30, 2025.

think that might help move things along and provide some certainty to getting the deal closed." Kilcoyne Tr. 183:8-24; 186:9-14. Mr. Kilcoyne's requests continued in 2025, when in a meeting with Mr. Bobo he "strongly encouraged EW [Edwards] to engage [r]egulators for remedies." JenaValve-2R-01189381. Although Mr. Kilcoyne thought Edwards "seemed receptive," *id.*, Edwards did not engage with the Bureau on potential remedies.

In our view, it is not too late to pursue a divestiture of JC Medical. The Bureau's competition concerns are predicated on Edwards owning both JC Medical and JenaValve. We believe that an orderly and complete divestiture of JC Medical to an approved buyer would address our competition concerns and clear the path for Edwards to consummate its proposed acquisition of JenaValve.[1]

The Bureau encourages Edwards to reconsider its position on a JC Medical divestiture before the parties move further down the litigation path.

Sincerely,

Daniel Guarnera
Director, Bureau of Competition
Federal Trade Commission

PX0061 at 002

PX2370 (JVT) at 002

From: Patel, Ruchit <Ruchit.Patel@ropesgray.com>
Sent: Monday, February 3, 2025 6:39 PM
To: Bock, Patrick <pbock@cgsh.com>; Calsyn, Jeremy J. <jcalsyn@cgsh.com>
Cc: McFalls, Michael S. <Michael.McFalls@ropesgray.com>; Bosch, Wolfgang (Gleiss Lutz) <wolfgang.bosch@gleisslutz.com>
Subject: RE: Edwards/JenaValve

Patrick,

We don't agree with your analysis of whether Edwards is under an obligation to divest. The Merger
was negotiated and agreed at a time when Jvalve was kept secret from us. As such, the clause you refer to w
intended to apply to, nor does it apply to, Edward's deliberately concealed acquisition of Jvalve, which was s
signed
and gi
Edwar

furthe
caused
possib
Gottlie
Agreer

divesti
that yo

ROPES & GRAY

"In these circumstances, and given that we would not be in this situation but for your concealed deal, we expect a Court of Equity to oblige Edwards to divest."

Memorandum Opinion Granting Motion to Compel

MEMORANDUM OPINION

GRANTING PLAINTIFF'S MOTION TO COMPEL DISCOVERY RESPONSES FROM DEFENDANT JENAVALVE TECHNOLOGY, INC.

[redacted]

ECF 078 at 005

PDX001-053

What Are Edwards' Incentives?

PX1137 (EW) at 004

PDX001-054

Edwards' Actions Speak for Themselves

Chat description: Original chat name: [redacted]

PX1044 (EW)

Chat type	IMessage/Sms
Private chat	no
Transcript timezone	(UTC) Coordinated Universal Time
Transcript start	2024-07-25 01:15:11
Transcript end	2024-07-25 03:50:49
Transcript participants	4
Initial participants	Don Bobo [redacted] Don Bobo [redacted] John Kilcone [redacted] Don Bobo [redacted]

Timestamp	Sender	Recipients	Message text
2024-07-25 01:15:11	[redacted]	Don Bobo [redacted] Don Bobo [redacted] John Kilcone	Don Can you share with me if JC is done or pending? Thanks John
2024-07-25 03:49:04	[redacted]	Don Bobo [redacted] Don Bobo [redacted] John Kilcone	Done
2024-07-25 03:49:57	[redacted]	Don Bobo [redacted] Don Bobo [redacted] John Kilcone	No HSR review?
2024-07-25 03:50:49	Don Bobo [redacted]	Don Bobo [redacted] Don Bobo [redacted] John Kilcone	Nope below the threshold! Intentional

Nickname Name Surname E-mail Source PID Type

"No HSR review?"

"Nope below the threshold! Intentional"

Don Bobo Jr.
CVP, Edwards

Q Above Mr. Dahl's email, you wrote "Thanks Andy. Keep me posted if our view changes."
You wanted to know if PwC advised that JC Medical's name had to be disclosed in Edwards' SEC filing?
MR. LIPTON: Objection to form.
Go ahead.
THE WITNESS: Yes.

Bobo (EW) Dep. 245:2-9

Edwards Slowing Down JenaValve Post-Merger Agreement

Bernard Zovighian
Edwards CEO

Sent: 8/7/2025 4:06:01 PM

Disappointing ... knew it was risky ... we did our best ... nothing to regret
Plan the next steps

- How to make JC the first and best: dedicated ... Larry/Dan ... review the plan when ready
- How to close Jenavalve through litigation ... what should we improve ... Mark ... review
- Prepare for also losing ... Don/Dan/Mark
    - What are liable for ?
    - No know how, no funding
    - How can we further slow down
    - Strategy update: SLT, BoD, Investor Conf

PX1437 (EW)

PDX001-056

Edwards Is Sole Source of Financing for JenaValve

[redacted]

Sincerely,

GIBSON, DUNN & CRUTCHER LLP

PX2473 at 002

The Hail-Mary Argument: "The [W]eakened [C]ompetitor"

"The 'weakened competitor' argument . . . . has been described as the 'Hail-Mary pass of presumptively doomed mergers.'"

United States v. Aetna Inc., 240 F. Supp. 3d 1, 92 (D.D.C. 2017)

Lessons Learned: *FTC v. Novant*

"The evidence established conclusively that . . . there is no other suitor waiting to take on this challenge."

Defendants' Proposed Findings of Fact and Conclusions of Law at 52,
FTC v. Novant Health, Inc., No. 24-cv-00028 (W.D.N.C. 2024), Dkt. No. 245

APR 08 | MORE ON MERGERS & ACQUISITIONS

Duke buys CHS hospital for $284 million

Duke has assumed operations at the Mooresville, North Carolina-based hospital and its related businesses.

Iredell Health System Officially Purchases Davis Regional Psychiatric Hospital, Davis Regional Medical Center

Tuesday, October 1, 2024

PDX001-059

[redacted]

[redacted]

PX2547 (JVT) at 002

JenaValve's Views on Standalone Prospects

Q And so everything in this email you stand by today?

A I would stand up today in front of the company and I would basically take them through this list. And I would also explain that, if this de
doesn't close, that despite the fact t
bright because JenaValve has the o
it is going to be a mountain of work
take time and effort to raise the cap
people, get everyone trained, execu
manufacturing yields, shore up sup
train salespeople, get through the VAC committee at the hospitals and IDMs to build a business. It can be done.
down the road will undoubtedly end up as part of a larger organization somewhere else.

Dearen (JVT) Dep. 110:1-25

Courtney Darby [redacted] 8/1/2025, 6:53 PM

It's dawning on me that after this crap is announced, there might be contractual agreements that will kick in that apply to our relationship

rid of me that easy ! no contractual agreements in place that I have signed, other than a non compete ....Im happy to be able to see you Wednesday at the office ....

PX2257 (JVT) at 002

"I really am 50/50 on what will happen…either way, I expect fully us to launch this product and beyond…."

"And long term, this company will ultimately, after a lot of work, I believe become successful and at some point down the road will undoubtedly end up as part of a larger organization somewhere else."

Roadmap

1. Introduction
2. Legal Standard
3. Background
4. Market Definition
5. Prima Facie Case
6. Defendants Cannot Meet Their Burden
7. Competitive Effects
8. Equities

Competitive Effects

Daniel Sun
Sr. Director, JenaValve

Sean Kim [redacted] ▶ 7/25/2024, 3:30 PM
I don't buy this shit at all. EW is going to only keep one or the other. JC acquisition is a threat to us

Daniel Sun [redacted]

"They will see which one is better and kill the other"

That's what I'm saying. They will see which one is better and kill the other

PX2062 (JVT) at 002

PX1280 (EW) at 001

From:	Blessie Concepcion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=97FEC6AF09AB40C3BA249029F15B52B0-BLESSIE CON]
Sent:	8/1/2024 1:02:41 AM
To:	Jaime Wheeler [Jaime_Wheeler@edwards.com]; Jessica Wimbrow [Jessica_Wimbrow@Edwards.com]; Heather Prince [Heather_Prince@edwards.com]
Subject:	RE: AR London Mtg 31-Jul-2024

Please disregard prior email and refer to the updated version below.
I'll schedule time for us to review and align on next steps.
Thanks!

Key Pri ... 0
days) wi

"Not proceed with the ARTIST AR IR/LR RCT"

1.
a. [redacted]

"JCM: proceed with Gen 2 over JenaValve [redacted]

2.
a. Proceed with JOURNEY AR HR Pivotal trial: review protocol to ensure there are no major issues [redacted] device manufactured in China can be used in trial (need to improve [redacted] but cannot be used to commercialize in the US – need to transfer manufacturing from China to Canada or in-house

Blessie Concepcion
VP, Edwards

PDX001-063

Roadmap

1. Introduction
2. Legal Standard
3. Background
4. Market Definition
5. Prima Facie Case
6. Defendants Cannot Meet Their Burden
7. Competitive Effects
8. Equities

Weighing the Equities

"[I]f the merger were ultimately found to violate the Clayton Act, it would be impossible to recreate pre-merger competition."

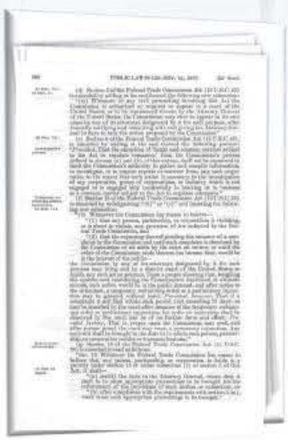
"In sum, weighing of the equities favors the FTC. If the merger is ultimately found to violate section 7 of the Clayton Act, it will be too late to preserve competition if no preliminary injunction has issued."

FTC v. H.J. Heinz Co., 246 F.3d 708, at 726-27 (D.C. Cir. 2001)

Weighing the Equities

"The equities will often weigh in favor of the FTC, since 'the public interest in effective enforcement of the antitrust laws' was Congress's specific 'public equity consideration' in enacting the provision."

FTC v. Whole Foods Mkt., Inc., 548 F.3d 1028, 1035 (D.C. Cir. 2008)



"If upon such hearing the Commission, Board, or Secretary, as the case may be, shall be of the opinion that any of the provisions of said sections have been or are being violated, it shall make a report in writing, in which it shall state its findings as to the facts, and shall issue and cause to be served on such person an order requiring such person to cease and desist from such violations, and divest itself of the stock, or other share capital, or assets, held or rid itself of the directors chosen contrary to the provisions of sections 18 and 19 of this title, if any there be in the manner and within the time fixed by said order."

15 U.S.C. § 21(b)

Weighing the Equities: Misuse of Confidential Information

Laksen,

I hope you had a good visit with your dad.

I was visiting California this week, not for work [redacted] Vivian called on Monday and said she had time available to update me on AWT, DFM and FEA/Fatigue. So, I went into the office on Wednesday afternoon to meet with her and she brought Aditya with her.

AWT and DFM are going well. I'll save the detail discussion for the second part. I'll start with the FEA and Fatigue.

Jena just finished a [redacted] They plan to submit the results this month (October) to the FDA. In contrast to AWT and DFM where they pre-negotiated the details of the procedure, for FEA/Fatigue there have been no FDA discussions. So, FDA will see this for first time when the results are submitted this month. Jena did not follow the ISO standard in a number of areas, and this concerns me.

requirement, although it is possible they have done more work than was communicated to me.]

5. I asked why they are comfortable with their study if it doesn't match ISO requirements and has little validation. They responded that they used some outside consultants who agreed and helped establish this approach.
6. [redacted]
7. The fatigue testing was done at G Rau in the Bay Area in Alan Pelton's lab. It was not full frame fatigue but done on segments of the frame called the rail area. The rail area was determined to be the highest stress area by the FEA. This is a legitimate approach except that I do not have evidence that the FEA is independently validated to accurately

5. [redacted] That's a little bit tight, but if they stay on top of the study, they can be writing the report while the valves are still cycling and just plug in the last set of data. We always say we're going to do that in our studies and it never works out that smoothly. There's a chance they'll miss that May 30th date by at least a little bit. By that time we should have ownership of JENA so we might be able to help get the report done.
6. The DFM samples will be loaded onto the machines next. They will probably take up to another three weeks to get the DFM samples all loaded and on their way.
7. I had expressed concern previously in how aggressive they were going to run the DFM. They have made changes to their pressure intervals and I am happier with the way

[redacted] is on track and looking good. Their fatigue and FEA didn't follow the USO. Standard and have some gaps. That's what I am digging into with Centera comparisons. I should have the full report for you either tonight or on Saturday.

G

CONFIDENTIAL TREATMENT REQUESTED EW-FTC-10102307 PX1243-001

CONFIDENTIAL TREATMENT REQUESTED EW-FTC-10102308 PX1243-002

CONFIDENTIAL TREATMENT REQUESTED EW-FTC-10102309 PX1243-003

CONFIDENTIAL TREATMENT REQUESTED EW-FTC-10102310 PX1243-004

PX1243 (EW) at 001

Weighing the Equities: JenaValve Accused Edwards of Fraud

From: Welsh, Peter L. <Peter.Welsh@ropesgray.com>
Sent: Saturday, February 8, 2025 6:25 AM
To: Lutz, Brian M. <BLutz@gibsondunn.com>
Cc: Nanda, Deepak <DNanda@gibsondunn.com>; jcalsyn@cgsh.com; Bock, Patrick <pbock@cgsh.com>; Davis, Colin B.

PX2371 (JVT) at 002

"In short, this narrative is pretextual and offered in a bad faith effort to deflect from Edwards' fraud in signing its deal with JenaValve while concealing from JenaValve and its advisors Edwards' near-simultaneous acquisition of J.C. Medical."

We entered MA after much negotiation as ***we believed*** that both factors were addressed

John Kilcoyne
JenaValve CEO

"**This is not the transaction we signed on for:** we would have negotiated different transaction terms (breakup fee, IP, divestiture) but more than likely no deal"

PX2373 (JVT) at 001

PDX001-068

Weighing Equities: Lives Saved

"Allegations that competition is not in the best interest of the Nation or an industry are not new to the courts."

FTC v. Alliant Techsystems, Inc., 808 F. Supp. 9, 23 (D.D.C. 1992)

Edwards: "a fat kid at the pie store…going to take them both"

PX1262 (EW) at 032

Larry Wood
Former CVP, Edwards

And I see it looks like maybe an AI-generated
baby image holding two pies?

"And we decided, you know, we were just going to be a fat kid at the pie store and we were just going to take them both."

Wood (EW) Dep. 93:17-25

PDX001-070

Thank You