IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC,	)	**C.A. NO. _____**
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
	)	
Defendants.	)	
	)	

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

Edwards v. Aortic Innovations
U.S. Patent 11,497,634
Edwards Ex. 1050

Plaintiff Aortic Innovations LLC ("AI" or "Plaintiff") files this Original Complaint against Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively "Edwards" or "Defendants") and hereby alleges as follows:

NATURE OF ACTION

1. AI alleges that Edwards has infringed and continues to infringe at least one claim of U.S. Patent Nos. 10,881,538 ("the '538 Patent"); 10,966,846 ("the '846 Patent"); 10,987,236 ("the '236 Patent"); and 11,129,735 ("the '735 Patent) (collectively, "Patents-in-Suit") (Exs. 1-4).

2. AI was founded in 2011 to develop the ideas of Dr. Ali Shahriari to help patients with damaged aortic valves. Dr. Shahriari is a cardiothoracic surgeon based in Florida who has practiced for more than 20 years and focused on treating the toughest cardiology cases. Originally from Sweden, Dr. Shahriari received his medical degree from University of Gothenburg Faculty of Medicine and trained at the Mayo Clinic and at Yale University. During his work as a cardiothoracic surgeon, Dr. Shahriari conceived of the inventions reflected in the Patents-in-Suit for performing transcatheter aortic valve replacements ("TAVR").

3. TAVR is a procedure where a replacement aortic heart valve is delivered by a catheter that is passed through an artery of a patient. Prior to TAVR, patients undergoing heart valve replacement would have their chest incised in an open heart procedure called Surgical Aortic Valve Repair ("SAVR"). SAVR often led to increased complications and was not deemed suitable for high risk patients who were often determined to be inoperable. The first TAVR device was approved in the United States by the Food and Drug Administration in 2011. Since that time, TAVR has become the leading choice for aortic valve replacement compared to the SAVR approach, with the number of TAVR procedures exceeding the number of SAVR procedures for the first time in 2019. Ex. 5, *TAVR Is Now Dominant Form of Aortic Valve Replacement in the*

United States (November 17, 2020), https://www.dicardiology.com/article/tavr-now-dominant-form-aortic-valve-replacement-united-states.

4. Foreseeing the promise of TAVR in his work as a cardiothoracic surgeon, Dr. Shahriari was at the forefront of TAVR technology development. By 2012, Dr. Shahriari conceived of TAVR devices that use an outer covering with fibers to promote sealing and aid in the prevention of paravalvular leaks—*e.g.*, leaks around the TAVR device. Since that time, Dr. Shahriari has worked on refining his ideas and—together with AI—has filed patent applications on his inventions in the United States and elsewhere. AI has secured numerous patents on Dr. Shahriari's revolutionary inventions in this technology space, including the Patents-in-Suit, which cover various TAVR assemblies and methods.

5. Edwards infringes the Patents-in-Suit through the manufacture, use, sale, offer for sale, and/or import of at least all versions and sizes of Edwards's Sapien 3 Ultra. On information and belief, Edwards's Sapien 3 Ultra is a transcatheter aortic heart valve deployed using a balloon catheter where the heart valve has an outer covering with fibers to aid in the prevention of paravalvular leaks. On information and belief, Edwards has marketed and sold Sapien 3 Ultra to others in the medical industry, including hospitals, medical centers, doctors, clinicians, care providers and patients, with knowledge of AI's intellectual property asserted herein. As a result of such actions, Edwards infringes, contributes to the infringement of, and/or induces the infringement of each of the Patents-in-Suit.

6. The similarities between the patent applications filed by Dr. Shahriari and the Sapien 3 Ultra product sold by Edwards are striking. The following images showing drawings from Dr. Shahriari's 2012 patent application (on the left) next to the Sapien 3 Ultra product (on the right) demonstrate these similarities:

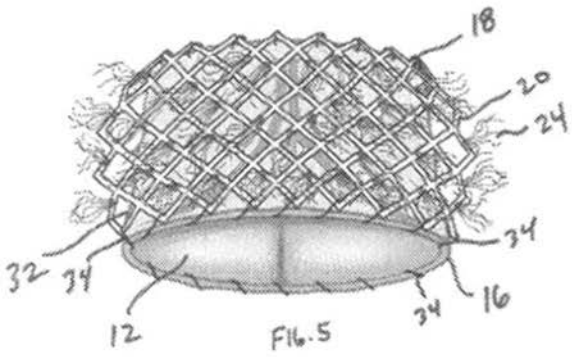


FIG. 5

Compare Ex. 6, U.S. Prov. Pat. App. No. 61/723,446, Figure 5 with Ex. 7, Sapien 3 Ultra, Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1.

PARTIES

7. Plaintiff Aortic Innovations LLC is a corporation organized under the laws of the State of Florida, with a principal place of business in Hillsboro Beach, Florida.

8. On information and belief, Defendant Edwards Lifesciences Corporation is a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Edwards Way, Irvine, CA 92614. On information and belief, Edwards Lifesciences Corporation is registered with the Delaware Secretary of State to transact business in Delaware. On information and belief, Edwards Lifesciences Corporation maintains a registered agent in Delaware, namely The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Edwards Lifesciences Corporation is the ultimate parent company of Edwards Lifesciences LLC, Edwards Lifesciences (U.S.) Inc. and

other Edwards Lifesciences entities. On information and belief, Defendant Edwards Lifesciences Corporation is the registrant of the website www.newheartvalve.com.

9. On information and belief, Defendant Edwards Lifesciences LLC is a limited liability company organized under the laws of the state of Delaware, with its principal place of business at 1 Edwards Way, Irvine, CA 92614. On information and belief, Edwards Lifesciences LLC is registered with the Delaware Secretary of State to transact business in Delaware, namely The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Edwards Lifesciences LLC is a wholly-owned subsidiary of Edwards Lifesciences Corporation and/or Edwards Lifesciences (U.S.) Inc. On information and belief, Defendant Edwards Lifesciences LLC is the registrant of the website www.edwards.com.

10. On information and belief, Defendant Edwards Lifesciences (U.S.) Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Edwards Way, Irvine, CA 92614. On information and belief, Edwards Lifesciences (U.S.) Inc. is registered with the Delaware Secretary of State to transact business in Delaware, namely The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Edwards Lifesciences (U.S.) Inc. is a wholly-owned subsidiary of Edwards Lifesciences Corporation.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over the patent infringement claims asserted in this case under 28 U.S.C. §§ 1331 and 1338.

12. This Court has personal jurisdiction over each named Edwards entity. Each named Edwards entity is incorporated in, present within, and/or has minimum contacts within the State of Delaware and this judicial district and has purposefully availed itself of the privileges of

conducting business in the State of Delaware and in this judicial district. Further, AI's causes of action arise directly from Defendants' business contacts and other activities in the State of Delaware and in this judicial district.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400 because Edwards has committed, and continues to commit, acts of infringement in this District and is incorporated in and has regular and established places of business in this District. On information and belief, each of the named Edwards entities maintains regular and established places of business in the District including at its affiliated hospitals in this District. Further, venue is proper because Edwards conducts substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct and/or deriving substantial revenue from goods and services provided to individuals in Delaware and this District.

14. On information and belief, Edwards has employees working in the District of Delaware, including employees directly involved with, testing, sales, importation, training and operations of the Sapien 3 Ultra—an accused infringing device in this matter. On information and belief, for example, Edwards employs clinical field and sales specialists that work at hospitals in this District.[1]

15. Edwards also conducts business within the District of Delaware. For example, on information and belief, Edwards's employees operating within this District solicit orders for Edwards's products; demonstrate Edwards's products; maintain an inventory of Edwards's

[1] Ex. 8, https://www.linkedin.com/in/rich-steigerwalt-077bbb52/ (Senior Field Clinical Specialist in transcatheter aortic valves).

products; educate and assist physicians with TAVR procedures; and/or fill orders from their inventory of Edwards's products within this District.

16. On information and belief, Edwards also maintains regular and established places of business in the District of Delaware at its affiliated hospitals. For example, on information and belief, Edwards maintains a website[2,3] identifying and directing potential patients in need of TAVR to the affiliated hospitals in the District of Delaware—including the Center for Heart and Vascular Health in Newark, DE and Bayhealth Medical Center in Dover, DE[4]—that provide the Edwards Sapien 3 Ultra.

17. Further, on information and belief, Edwards's employees provide onsite education and outreach and participate in TAVR procedures at Edwards affiliated hospitals in this District. These employees help select new patients for TAVR procedures, including with the Sapien 3 Ultra. Further, on information and belief, Edwards employees participate in surgical interventions involving TAVR devices, including the Sapien 3 Ultra, including preparing the devices prior to insertion by the doctor into the patient.

18. On information and belief, Edwards has created a sales, distribution, implantation, and service system comprising substantial resources within the District of Delaware. Through its distribution channels, Edwards introduces infringing products into the stream of commerce with

[2] Ex. 9, https://newheartvalve.com/find-tavr-hospital/ (last accessed Sept. 28, 2021).

[3] The website indicates that TAVR procedures are performed at identified hospitals. TAVR includes Edwards's SAPIEN 3 Transcatheter Heart Valve ("THV") System and Edwards's SAPIEN 3 Ultra THV System. *See* Ex. 10.

[4] Ex. 10, TAVR Information provided by Edwards for the Center for Heart and Vascular Health in Newark, DE and Bayhealth Medical Center in Dover, DE.

the knowledge, expectation, and intent that they will be sold, implanted, and used in the United States, including in the State of Delaware and in this District.

19. On information and belief, acts of infringement take place in this District. As noted above, on information and belief, Edwards conducts business through several hospitals in the District of Delaware. On information and belief, Edwards sells Sapien 3 Ultra devices to hospitals and/or medical staff located at least at the hospitals listed above. Those devices are then resold to and inserted into patients. Each sale, the operation, and the continued use by the patient constitutes an infringing use in the District of Delaware.

20. In addition, on information and belief, Edwards has previously availed itself of this District in the past 10 years by bringing and defending against numerous patent infringement matters—including cases involving similar subject matter to that in the instant suit—in this District as reflected in the table below:

Case Name	Case Filing Date	Edwards Party
Abbott Cardiovascular Systems. Inc. et al v. Edwards Lifesciences Corporation, et al., 1-19-cv-00149 (DDE)	Jan. 28, 2019	Defendant
Boston Scientific Scimed. Inc. v. Edwards Lifesciences LLC, 1-18-cv-01535 (DDE)	Oct. 03, 2018	Defendant
Edwards Lifesciences LLC v. Boston Scientific Corp., 1-18-cv-01294 (DDE)	Aug. 22, 2018	Plaintiff
Kaldren LLC v. Edwards Lifesciences Corporation, 1-17-cv-01268 (DDE)	Sep. 05, 2017	Defendant
Boston Scientific Corporation, et al. v. Edwards Lifesciences Corporation, 1-16-cv-00275 (DDE)	Apr. 19, 2016	Defendant
Endoheart AG v. Edwards Lifesciences Corporation, 1-14-cv-01473 (DDE)	Dec. 10, 2014	Defendant

Edwards Lifesciences LLC, et al. v. Medtronic Corevalve LLC, et al., 1-12-cv-00023 (DDE)	Jan. 11, 2012	Plaintiff

This further demonstrates that jurisdiction and venue are proper and convenient for Edwards in this District.

THE AORTIC INNOVATIONS PATENTS

21. On January 5, 2021, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 10,881,538 ("the '538 Patent"), entitled "Method for Aortic Repair and Aortic Replacement," to inventor Dr. Ali Shahriari. AI owns all rights to the '538 Patent necessary to bring this action. A true and correct copy of the '538 Patent is attached hereto as Exhibit 1 and incorporated herein by reference.

22. On April 6, 2021, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 10,966,846 ("the '846 Patent"), entitled "Device for Endovascular Aortic Repair," to inventor Dr. Ali Shahriari. AI owns all rights to the '846 Patent necessary to bring this action. A true and correct copy of the '846 Patent is attached hereto as Exhibit 2 and incorporated herein by reference.

23. On April 27, 2021, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 10,987,236 ("the '236 Patent"), entitled "Transcatheter Aortic Valve Repair Having Improved Paravalvular Seal," to inventor Dr. Ali Shahriari. AI owns all rights to the '236 Patent necessary to bring this action. A true and correct copy of the '236 Patent is attached hereto as Exhibit 3 and incorporated herein by reference.

24. On September 28, 2021, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 11,129,735 ("the '735 Patent"), entitled "Transcatheter Valve Repair

Having Improved Paravalvular Seal," to inventor Dr. Ali Shahriari. AI owns all rights to the '735 Patent necessary to bring this action. A true and correct copy of the '735 Patent is attached hereto as Exhibit 4 and incorporated herein by reference.

FACTUAL BACKGROUND

A. DR. SHAHRIARI'S TAVR INVENTIONS

25. Dr. Shahriari is the sole inventor of the Patents-in-Suit. Dr. Shahriari conceived of novel concepts related to endovascular aortic repair starting in 2011. Specifically, Dr. Shahriari invented a transcatheter aortic valve replacement ("TAVR") device and an aneurysm treatment device in 2011 and further refined his inventions thereafter.

26. Dr. Shahriari filed patent applications on a TAVR having outwardly or radially extending fibers for treating paravalvular leaks in 2012. As Dr. Shahriari explained in his 2012 patent application, the "fibers … aid in preventing paravalvular leaks and migration of the transcatheter valve device … within the aortic walls." Ex. 6, U.S. Prov. Appl. 61/723,446 at [0024]. Dr. Shahriari's first issued patent directed towards a TAVR having outwardly extending fibers was granted in January 2015. *See* Ex. 11, U.S. Patent 8,940,040. The addition of outwardly extending fibers on an outside surface of the stent frame addressed many shortcomings of conventional TAVR devices, as discussed further below.

B. DR. SHAHRIARI'S INTERACTIONS WITH EDWARDS AND EDWARDS'S KNOWLEDGE OF AI'S PATENTS

27. While working on his TAVR inventions, Dr. Shahriari also worked on another device called the Ascyrus Medical Device Stent ("AMDS") on behalf of Ascyrus Medical, LLC ("Ascyrus"), a company that Dr. Shahriari had formed. The AMDS is life changing technology designed to repair type-A dissections in the aorta—*i.e.*, tears in the ascending aorta where it exits the aortic valve.

28. Based on interest and funding from investors, Dr. Shahriari focused his initial efforts on bringing the AMDS to market. After bringing the AMDS to market, Dr. Shahriari planned to return his focus to AI and bringing his TAVR designs to market.

29. Edwards was aware of AI's patent applications directed towards a TAVR design with outwardly extending fibers at least as early as November, 2014.

30. Specifically, Edwards filed U.S. Patent Application No. 14/033,075 ("the Edwards '075 Application") on September 20, 2013. Ex. 12 at 003-036. The Edwards '075 Application is directed towards a combination implant that includes a TAVR device with an additional stent for ascending aorta repair.

31. During prosecution of the Edwards '075 Application, Edwards cited WIPO Patent Publication WO2013/086132 ("the AI '132 Application") (Ex. 13) by Aortic Innovations in an Information Disclosure Statement filed on November 13, 2014.

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2013/086132	WO	A1	2013-06-13	Aortic Innovations Llc		☐

Ex. 12 at 001.

32. The November 14, 2014 Information Disclosure Statement was filed by Pui Tong Ho, who, on information and belief, was and is in-house Intellectual Property Counsel for Edwards.

33. The AI '132 Application contains virtually the same disclosure and subject matter as the Patents-in-Suit. Compare Ex. 13 to Exs. 1-4.

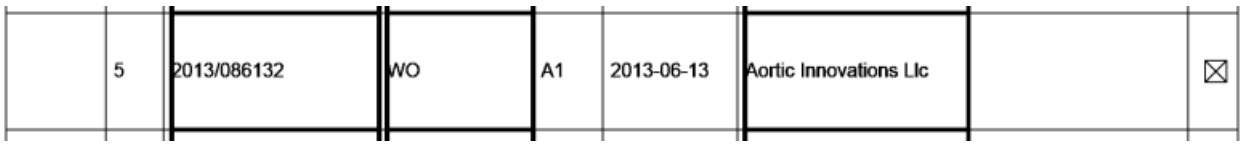
34. Claim 16 of the AI '132 Application, as an example, recites:

16. The transcatheter valve of claim 15, wherein a plurality of fibers are attached to the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

Ex. 13, AI '132 Application, claim 16.

35. Additionally, Edwards filed U.S. Patent Application No. 15/445,651 ("the Edwards '651 Application") on February 28, 2017. Ex. 14 at 005-040. The Edwards '651 Application is a continuation of the Edwards '075 Application.

36. During prosecution of the Edwards '651 Application, Edwards cited the AI '132 Application in an Information Disclosure Statement filed on March 30, 2017.



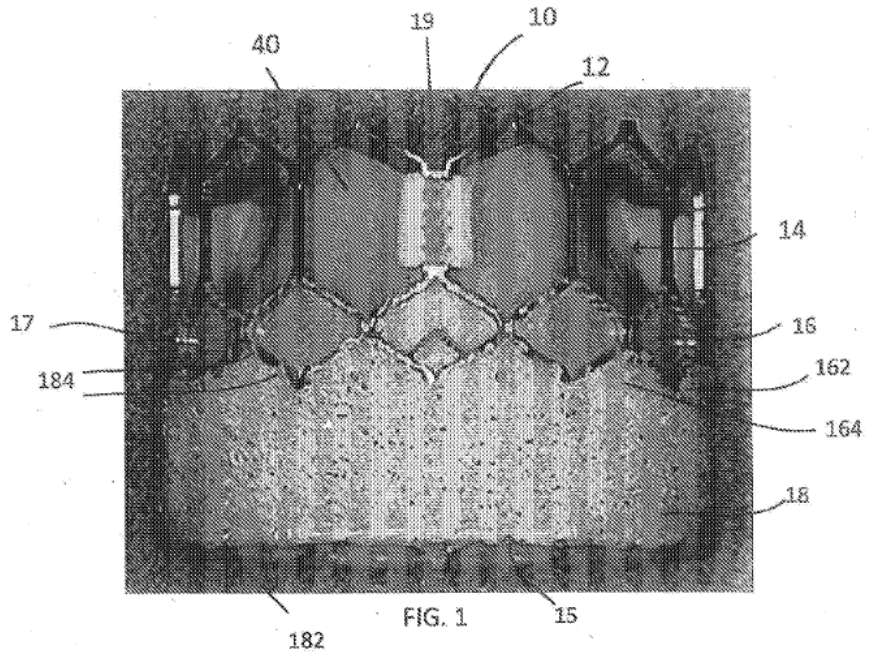
Ex. 14 at 001.

37. The March 30, 2017 Information Disclosure Statement was filed by Thomas C. Richardson, who, on information and belief, was and remains in-house Intellectual Property Counsel for Edwards.

38. Not only was Edwards aware of AI's patent and technology as a result of its patent prosecution activities, but also Edwards learned of Dr. Shahriari's inventions directly from discussions with Dr. Shahriari. Specifically, on or around early 2017, Dr. Shahriari contacted Edwards to discuss his AMDS device. Ex. 15. Specifically, on April 19, 2017, Dr. Shahriari sent an email to Donald Bobo and Larry Wood of Edwards. *Id*. On information and belief, Donald Bobo is Corporate Vice President of Strategy and Corporate Development for Edwards and Larry Wood is Corporate Vice President of Transcatheter Aortic Valve Replacement for Edwards.

39. In the April 19, 2017 email, Dr. Shahriari, in addition to discussing his AMDS work, also told Edwards that the "IP for modular use of a transcatheter valve with an aortic graft has been granted to us." *Id*. Edwards then arranged a conference call for May 2, 2017, to which Bernard Zovighian, Amir Blumenfeld, Jack Westhart, Mr. Wood, and Mr. Bobo were all invited. Ex. 16. On information and belief, Mr. Zovighian is now and was Corporate VP and General Manager of Transcatheter Mitral and Tricuspid Therapy of Edwards, Dr. Blumenfeld is now a Senior Director of Discovery at Edwards, and Mr. Westhart is Senior Director of Corporate Development. Despite Dr. Shahriari's intent to discuss Ascyrus's inventions and the AMDS with Edwards during the conference call, Edwards, and specifically, Dr. Blumenfeld, asked for information on AI's inventions and the AI patents and expressed little to no interest in Ascyrus or the AMDS. On information and belief, based on the questions asked during the 2017 conference call, Edwards, including specifically, Dr. Blumenfeld, were aware of AI's patents and the inventions described therein.

40. On May 31, 2017, less than a month after the May 2, 2017 conference call between Dr. Shahriari and Edwards, Edwards filed a provisional patent application, U.S. Provisional Patent Application No. 62/513,348 ("the Edwards '348 Application"), on a TAVR design that included outwardly extending fibers. Ex. 17. FIG. 1 of the '348 Application is representative:



Ex. 17, U.S. Provisional Patent Application No. 62/513,348, 046, Figure 1.

41. Upon information and belief, the TAVR device shown in the Edwards '348 Application, specifically with reference to FIG. 1, is an example of the Edwards Sapien 3 Ultra TAVR, a valve produced by Edwards and sold in the United States, Canada, Europe, and other countries throughout the world. Edwards did not inform Dr. Shahriari during the May 2, 2017 conference call or thereafter that it was introducing a competing TAVR device or that its soon-to-be introduced TAVR device included fibers similar to the fibers described in the Aortic Innovations patents.

42. In October 2017, Philip Nowell, then Vice President of Global Business Strategy and Commercialization of Ascyrus Medical, who was aware of Edwards's interest in AI's TAVR

devices, sent an email to Mr. Bobo to discuss "other devices we have in development of which you are already aware following your earlier discussions with Dr. Shahriari." Ex. 18. Mr. Nowell received no response from Edwards.

43. Likewise in 2019, Dr. Shahriari sent an email to Mr. Bobo to further follow up on the AMDS, but again, Edwards did not respond. Ex. 19. Dr. Shahriari subsequently learned of Edwards's release of the Sapien 3 Ultra with an outwardly extending fiber seal and its use of AI's patented inventions.

44. Edwards's infringing Sapien 3 Ultra valve incorporating Dr. Shahriari's inventions was adopted by medical professionals soon after its launch, quickly establishing a foothold in the TAVR market. As a result of Edwards's misappropriations of Dr. Shahriari's inventions, AI was effectively precluded from bringing its TAVR device to market and selling its TAVR business.

45. Despite having knowledge of AI and Dr. Shahriari's TAVR inventions, following Edwards's discussions with Dr. Shahriari and its release of the Sapien 3 Ultra, Edwards has avoided public recognition of Dr. Shahriari's inventions and his patents since Edwards's initial discussions with Dr. Shahriari in May 2017.

46. For example, on August 31, 2018, Edwards filed U.S. Patent Application No. 16/120,112 ("the Edwards '112 Application"), which claims priority through intermediate applications to the Edwards '348 Application. Upon information and belief, the Edwards '112 Application is directed to TAVR devices and currently claims, among other things, an outer sealing member that includes "a plurality of pile yarns extending outwardly from the mesh layer." Ex. 20 at 001.

47. Upon information and belief, at least claim 1, the first independent claim of the Edwards ‘112 Application, is similar to the disclosure in the AI ‘132 Application and its related family members. *Id*.

48. Edwards, despite being aware of AI, Dr. Shahriari’s inventions, and at least the AI ’132 Application, has so far failed to cite the AI ’132 Application or family members thereof.

49. Upon information and belief, Edwards has intentionally avoided citation to the AI ‘132 Application and its family members during prosecution of the Edwards ‘112 Application in order to obscure its knowledge of the AI ‘132 Application and Dr. Shahriari’s inventions, despite the overlapping subject matter with the Edwards ’112 Application.

50. Similarly, Edwards filed U.S. Patent Application No. 16/902,373 (“the Edwards ’373 Application”) on June 16, 2020. Ex. 21. The Edwards ’373 Application claims priority through intermediate applications to a U.S. Provisional Patent Application No. 61/912,231 (“the Edwards ’231 Application”), filed on December 5, 2013. Ex. 21 at 003.

51. The Edwards ’373 Application is directed to a TAVR device and includes disclosure directed towards a “pile fabric” that forms a sealing skirt. This is illustrated in FIG. 38:

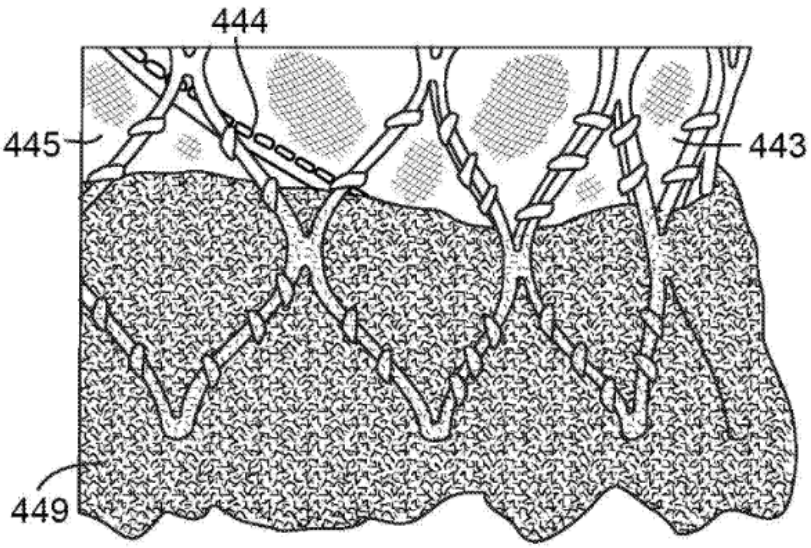


FIG. 38

Ex. 21, 071, Figure 38.

52. The Edwards ’373 Application currently claims, among other things, a “collapsible and expandable sealing skirt” that comprises “a pile fabric and can contact tissue surrounding the prosthetic valve when the prosthetic valve is implanted within a native valve annulus.” *Id.* at 047.

53. Edwards, despite being aware of AI, Dr. Shahriari’s inventions, and at least the ’132 Application by AI, has so far failed to cite the AI ’132 Application or family members thereof.

54. Upon information and belief, Edwards has intentionally avoided citation to the AI ’132 Application and its family members during prosecution of the Edwards ’373 Application in order to obscure its knowledge of the AI ‘132 Application and Dr. Shahriari’s inventions, despite the overlapping subject matter with the Edwards ’373 Application.

55. In addition, prior to filing suit, AI contacted Edwards in a good faith effort to license the AI patent portfolio. Specifically, on July 19, 2021, Dr. Shahriari sent an email to Mr. Bobo and Chief IP Counsel Keith Newburry expressly informing them of Edwards’s practice of the Patents-in-Suit and related patents in relation to the Sapien 3 Ultra (as well as Edwards’s practice of AI’s mitral valve patents in relation to Edwards’s Sapien M3 valve) and requesting the opportunity to discuss a potential license. Ex. 22. On information and belief, after receiving notice, Edwards has not ceased practicing the Patents-in-Suit or any other AI patents identified in AI’s July 19, 2021 email.

56. As such, Edwards knew, should have known, or was willfully blind as to the existence of the Patents-in-Suit and its potential infringement thereof at the time of Edwards’s infringing acts.

C. TAVR IMPROVEMENTS AND MARKET GROWTH

57. TAVR was not widely accepted technology in the field in 2011. The first FDA approved TAVR device was not approved until November, 2011, less than a decade ago for extreme risk patients. TAVR was then approved for intermediate risk patients in 2016. Following further advancements in TAVR technology, the FDA approved TAVR for low risk patients in 2019. Ex. 23, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S085.

58. Since its original development in the early 2000's, TAVR has suffered from various shortcomings. One of the most discussed shortcomings is leakage around the replacement valve assembly. Ex. 24, S. Lerakis, MD, et al., Paravalvular Aortic Leak After Transcatheter Aortic Valve Replacement, Circulation. 2013;127:397–407 (January 22, 2013), https ://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.112.142000). This leakage is termed paravalvular leakage and/or paravalvular regurgitation (collectively "PVL"). PVL can be deadly and is considered one of the largest drawbacks associated with TAVR. Some studies report a PVL rate of around 48% in predicate TAVR devices. *Id*.

59. Despite this and other shortcomings of early TAVR devices, the advancement of TAVR has been significant, with TAVR procedures outpacing SAVR procedures for the first time in 2019. Ex. 5, TAVR Is Now Dominant Form of Aortic Valve Replacement in the United States (November 17, 2020), https://www.dicardiology.com/article/tavr-now-dominant-form-aortic-valve-replacement-united-states. On information and belief, the continued success of TAVR relative to SAVR is in large part due to the adoption of outer sealing skirts including those with radially or outwardly extending fibers, which have been found to dramatically reduce PVL.

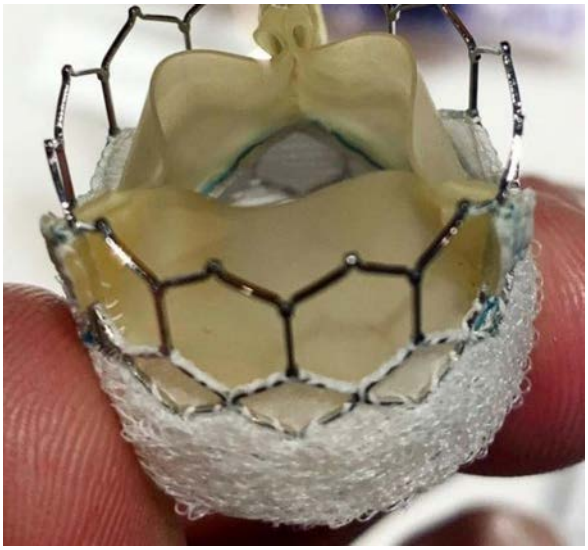
60. Edwards has released several TAVR devices on the market. One of the first TAVR devices produced by Edwards was the Sapien XT valve. Ex. 25, Edwards Lifesciences Launching SAPIEN XT Valve In The U.S. (June 16, 2014), https://www.prnewswire.com/news-releases/edwards-lifesciences-launching-sapien-xt-valve-in-the-us-263350811.html. This valve did not have an outer seal on the TAVR. A representative image of the Sapien XT is shown below:

Ex. 26, https://www.edwards.com/gb/devices/heart-valves/sapien-xt-valve.

61. Edwards also introduced the Sapien 3 TAVR, which included a loosely fit outer skirt with openings that would provide minimal sealing to attempt to address PVL. On information and belief, the sealing was accomplished by the billowing of the skirt, and retrograde blood flow into the skirt that further radially expanded the outer skirt. On information and belief, the Sapien 3 did not have any outwardly extending fibers on its outer skirt to provide for sealing. A representative image of the Sapien 3 is shown below:

Ex. 27, https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3.

62. Edwards received FDA approval for the Sapien 3 Ultra TAVR—which practices the inventions of the Patents-in-Suit—in December, 2018. Ex. 28, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S074. The Sapien 3 Ultra is a TAVR that has a heightened outer skirt made of radially or outwardly extending fibers. Representative images of the Sapien 3 Ultra are shown below:



Ex. 29, Sapien 3 Ultra image available at https://www.instagram.com/p/BysjboFBLiG/.

Ex. 30, Sapien 3 Ultra image by Calin Iulian, MD, available at https:// www.instagram.com/p/CMwNvDgpFIQ/?igshid=1u39mbgvqtvj9.

63. On information and belief, the Edwards Sapien 3 Ultra has quickly overtaken Edwards's predecessor TAVR device, the Sapien 3, and represents more than two-thirds of Edwards's global TAVR sales. Indeed, in the Edwards earnings call for the Fourth Quarter of 2020, CEO Michael Mussallem stated, "SAPIEN 3 Ultra now represents more than two-thirds of our global TAVR sales and physician feedback on ease of use and improved paravalvular leak performance remains outstanding." Ex. 31, Edwards Lifesciences Corp. (EW) Q4 2020 Earnings Call Transcript (January 27, 2021), https://www.fool.com/earnings/call-transcripts/2021/01/27/edwards-lifesciences-corp-ew-q4-2020-earnings-call/.[5]

[5] Edwards Lifesciences Corporation's earnings call discussed sales included in Edwards Lifesciences Corporation's Form 10-K for the Fiscal Year Ending Dec. 31, 2020. Edwards Lifesciences Corporation's 10-Ks and Annual Reports specify that "'Edwards' and 'Edwards Lifesciences' refer to Edwards Lifesciences Corporation and its subsidiaries. Ex. 36 at 1. Exhibit 21.1 of Edwards 10-K specifies that Edwards Lifesciences LLC is a subsidiary of Edwards which is included in these filings.

64. On information and belief, the market cap of Edwards as measured by the New York Stock Exchange has increased from approximately 31.00 Billion USD at the time of the initial FDA approval of the Sapien 3 Ultra to approximately 74.00 Billion USD as of the date of filing this complaint. https://ycharts.com/companies/EW/market_cap.

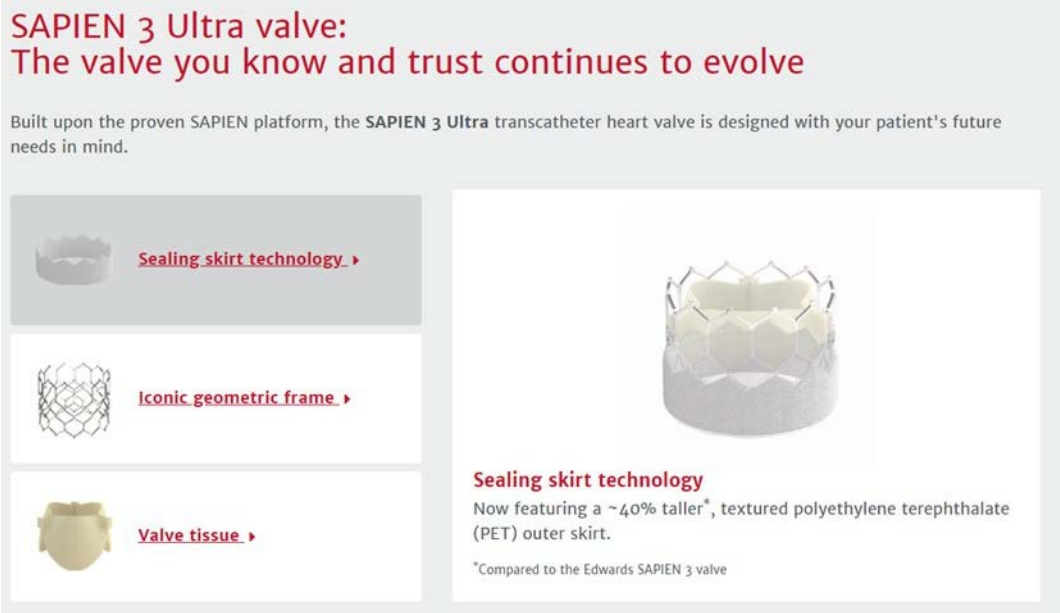
65. On information and belief, the rapid adoption of Sapien 3 Ultra is due in large part to the heightened outer skirt with radially or outwardly extending fibers. According to Edwards's studies, the fiber skirt of the Sapien 3 Ultra has led to a significant reduction in PVL. According to a recently released study, PVL in the predecessor Sapien 3 valve was 48%, whereas PVL was only 11.2% in Sapien 3 Ultra, representing an approximate 75% reduction in PVL. Ex. 32, Minimizing Paravalvular Regurgitation With the Novel SAPIEN 3 Ultra TAVR Prosthesis: A Real-World Comparison Study (March 18, 2021), https: //www.frontiersin.org/articles/ 10.3389/fcvm.2021.623146/full.

EDWARDS'S ACCUSED PRODUCTS

A. EDWARDS MAKES, IMPORTS, USES, SELLS, AND/OR OFFERS FOR SALE PRODUCTS THAT INFRINGE THE PATENTS-IN-SUIT.

66. Edwards makes, imports, uses, sells, and/or offers for sale TAVR devices that infringe at least one claim of each of the Patents-in-Suit ("Accused Products").

67. For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells a TAVR device called Sapien 3 Ultra. An image of the Sapien 3 Ultra TAVR device and components thereof are shown below:



Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra.

68. On information and belief, Edwards received FDA approval for the Sapien 3 Ultra in December 2018. Ex. 28, https: //www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P140031S074.

69. On information and belief, Edwards manufacturers and/or assembles Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and Ireland. *See* Ex. 34, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P140031S099; Ex. 35, https:// www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S102; Edwards Lifesciences Corporation, Annual Report (Form 10-K) (December 31, 2020), available at Ex. 36, https://sec.report/Document/0001099800-21-000007/ (including financial information on "Edwards Lifesciences Corporation and its subsidiaries", see Footnote 5, supra).

70. On information and belief, Edwards supplies in and/or from the United States some or all of the components of the Sapien 3 Ultra in such a manner that such components will be combined outside of the United States to form the Sapien 3 Ultra. Upon information and belief,

such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in Costa Rica and at other non-U.S. locations.

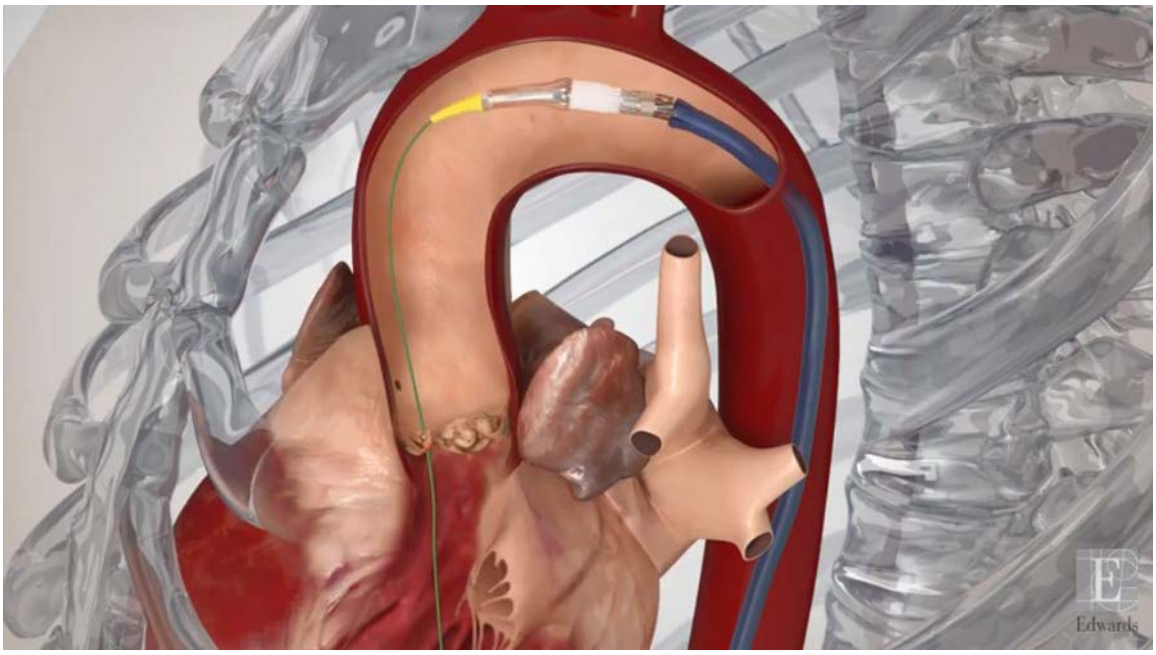
71. On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States directly, and/or through sales representatives or distributors, and provides instructions on how to deploy and use Sapien 3 Ultra. For example, Edwards advertises its Sapien 3 Ultra product on public webpages registered to Edwards's parent corporation and provides public videos branded and/or sponsored by Edwards. *See, e.g.*, Ex. 33, https: //www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra; Ex. 37, https://www.youtube.com/watch?v=o3whx7CdM3I at 3:05 (accessed Sept. 23, 2021); Ex. 38, https://newheartvalve.com/; Ex. 39, https://www.tavrbyedwards.com/. Edwards Lifesciences Corporation's recent SEC filings also include repeated mentions of the Sapien 3 Ultra product. *See* Edwards Lifesciences Corporation, Form 10-K (Dec. 31, 2020) at 2, 24[6], available at Ex. 36; Edwards Lifesciences Corporation Form 10-K (Dec. 31, 2019) at 2, 24, 26, available at Ex. 40, https:// www.sec.gov/ix?doc=/Archives/edgar/data/0001099800/000109980020000005/ew10-kq42019.htm[7]. On information and belief, advertising and brochures from Edwards Lifesciences Corporation are directed towards selling products manufactured and owned by Edwards Lifesciences LLC.

72. Edwards also regularly includes information concerning the production and sale of Sapien 3 Ultra in Edwards Lifesciences Corporation's SEC filings and presentations to Edwards's investors. *See, e.g.*, Edwards Lifesciences Corporation Form 10-K (2020) at 2, 24, available at Ex. 36; Edwards Lifesciences Corporation Form 10-K (2019) at 2, 24, 26, available at

[6] *See* Footnote 5, *supra*.
[7] *See* Footnote 5, *supra*.

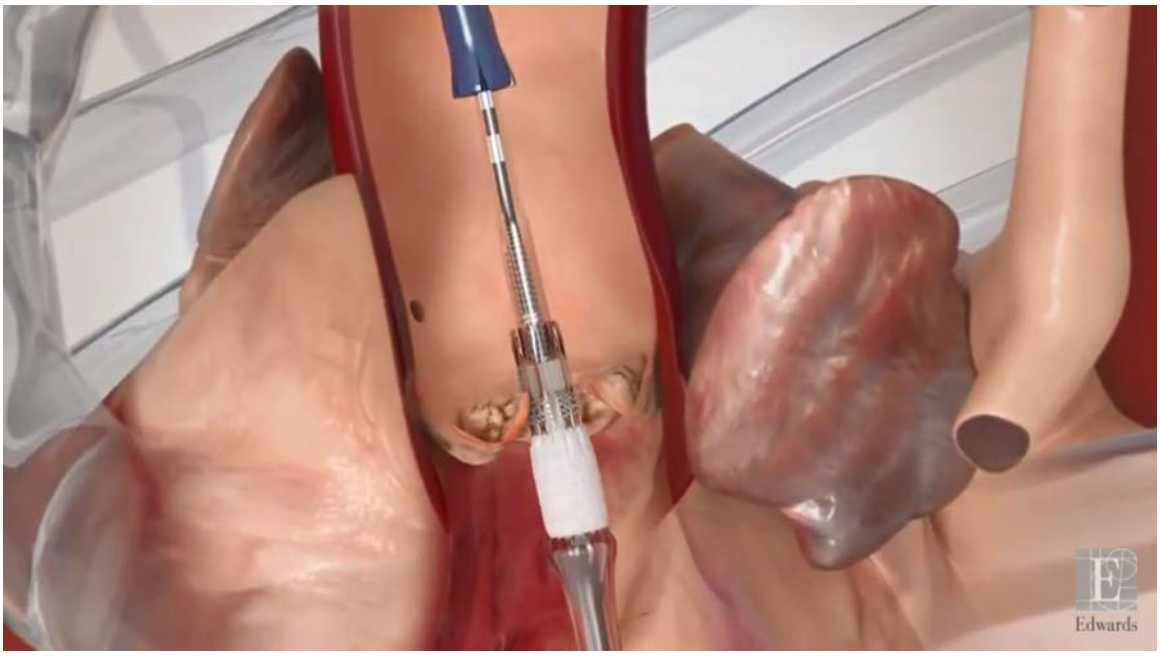
Ex. 40; 2020 Investor Conference: Transcatheter Aortic Heart Valves (December 10, 2020), Ex. 41, https://s27.q4cdn.com/788244549/files/doc_presentations/2020_IC_Binder.pdf; Edwards Lifesciences 39th Annual J.P. Morgan Healthcare Conference (January 11, 2021), Ex. 42, https://s27.q4cdn.com/788244549/files/doc_presentations/EW-JPMorgan-2021_vFINAL.pdf[8].

73. Use of Sapien 3 Ultra is depicted in a video provided by Edwards titled "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I; *see also* Ex. 37. The following images of Sapien 3 Ultra are screenshots captured from this video demonstrating a TAVR procedure with the Sapien 3 Ultra.

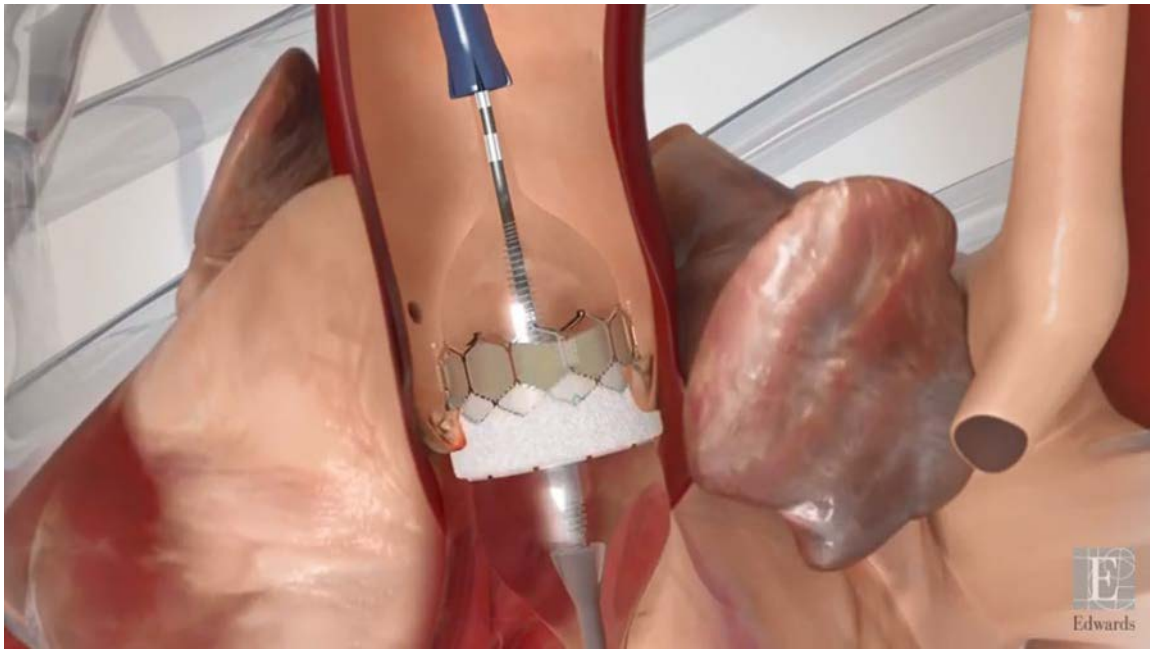


Id. at 1:08.

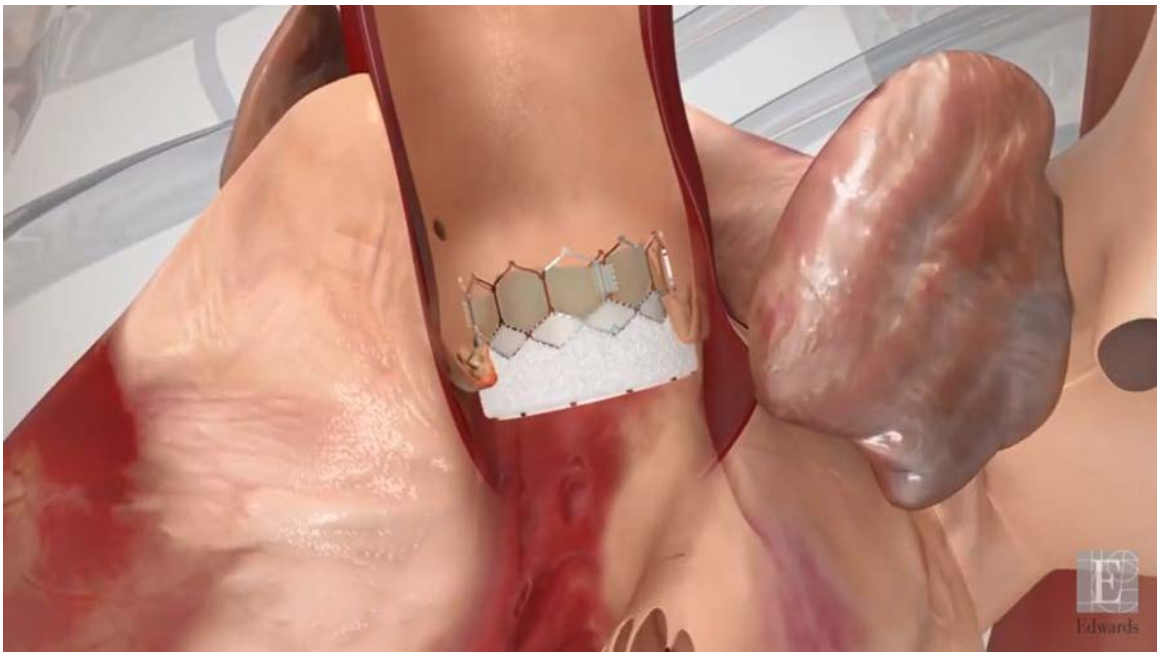
[8] *See* Footnote 5, *supra*, noting that such information includes information from Edwards Lifesciences LLC.



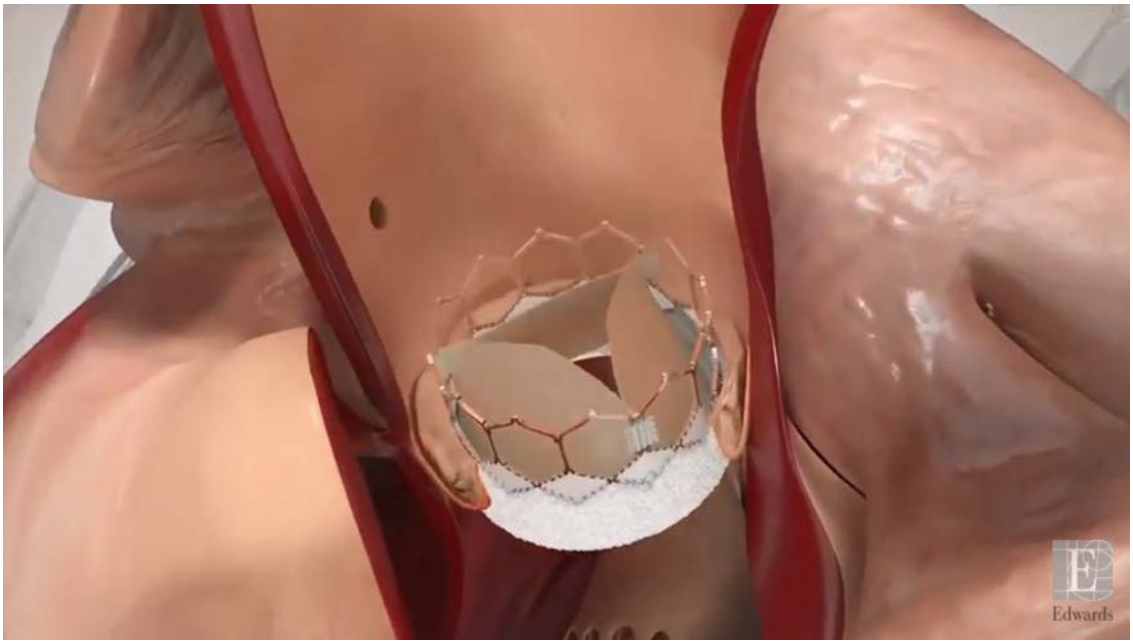
Id. at 1:13.



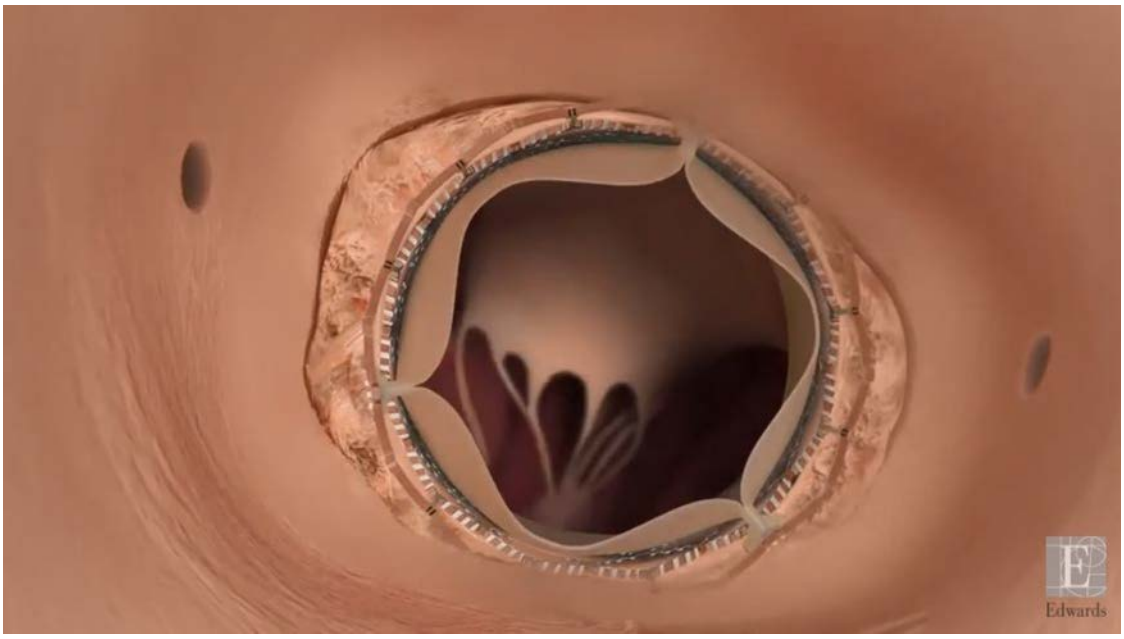
Id. at 1:25.



Id. at 1:48.

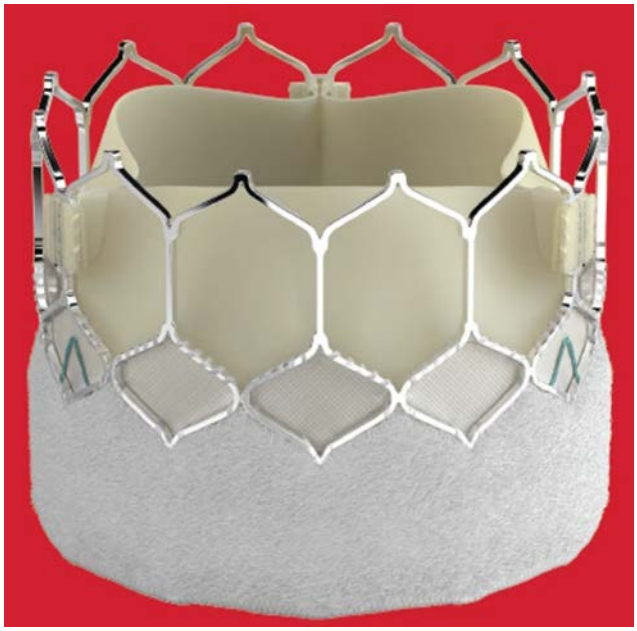


Id. at 1:54.



Id. at 1:59.

74. On information and belief, the Sapien 3 Ultra includes an outer frame made from a metallic material that has multiple open cell portions.



Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1-2, Ex. 43, https://edwardseducation.com/eacts2020/documents/PP--EU-0118%20v1.0%20S3%20Ultra%20on%20Commander%20Implanter%20Brochure.pdf.

75. On information and belief, the Edwards Sapien 3 Ultra outer frame is formed from a cobalt-chromium metallic alloy in an open cell configuration.

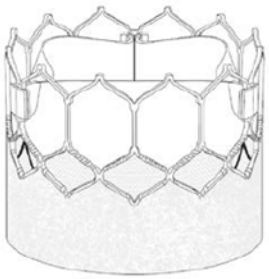
1.0 Device Description

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve (THV) System

The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve system consists of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves and delivery systems.

- **Edwards SAPIEN 3 Ultra Transcatheter Heart Valve – (Figure 1)**

The Edwards SAPIEN 3 Ultra transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) inner and outer fabric skirts. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.



9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

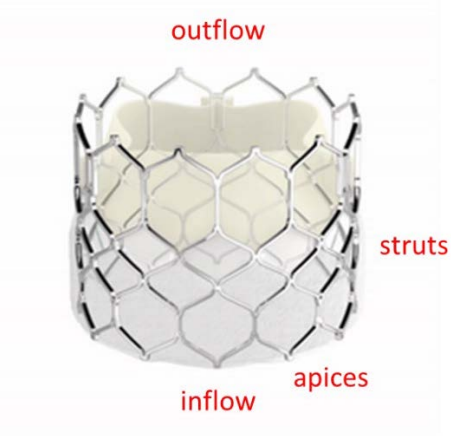
Table 1

Valve Size	Valve Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm

Sapien 3 Ultra Instructions for Use at 2, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf; *see also* Sapien 3 Ultra

(PMA P140031/S085) FDA Summary of Safety and Effectiveness Data at 2-3, Ex. 45, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.

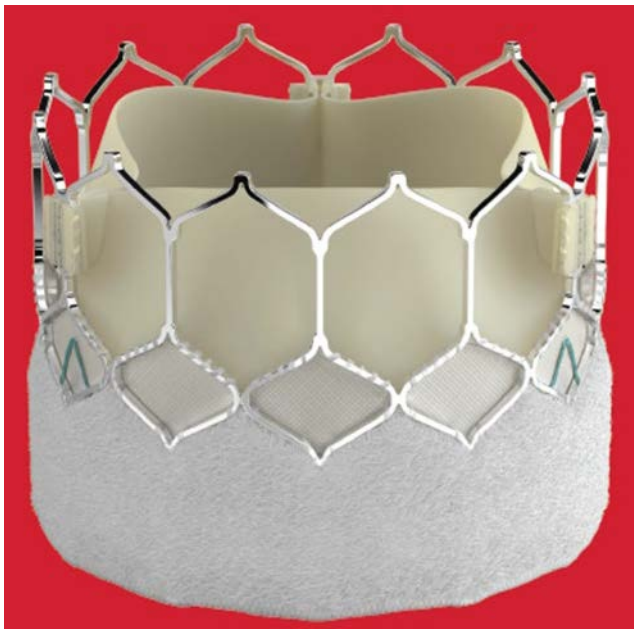
76. On information and belief, the Edwards Sapien 3 Ultra outer frame has an inflow end and an outflow end and is formed by a plurality of struts that adjoin each other at the inflow end to form apices.



Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added).

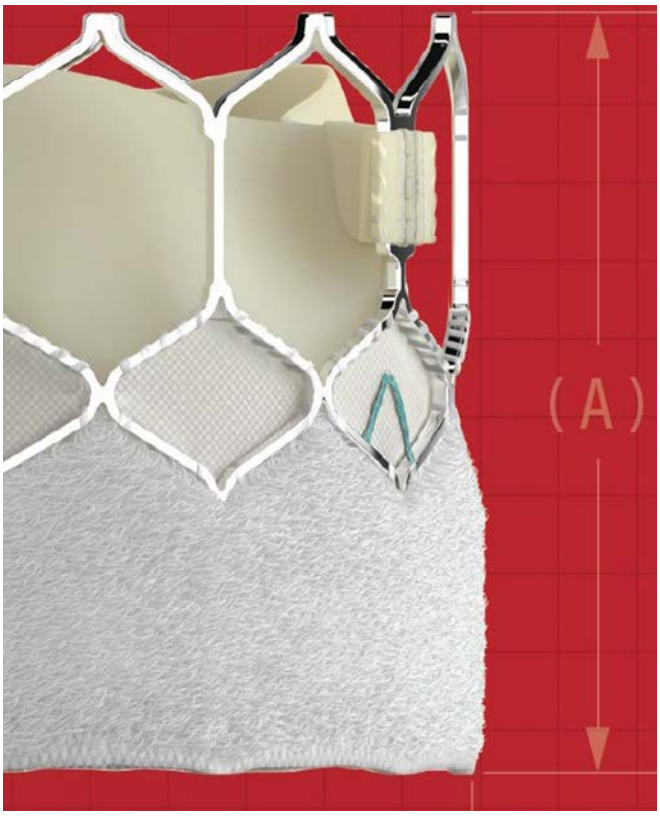
77. On information and belief, the Edwards Sapien 3 Ultra includes an inner frame that houses a prosthetic heart valve having leaflets. Sapien 3 Ultra Instructions for Use at 2, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf; *see also* Sapien 3 Ultra (PMA P140031/S085) FDA Summary of Safety and Effectiveness Data at 2-3, Ex. 45, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.

78. On information and belief, the Sapien 3 Ultra inner frame graft covering is made from a polyethylene terephthalate (PET) internal fabric skirt that extends around and provides sealing for a bovine prosthetic heart valve. *Id.* Upon information and belief, the Sapien 3 Ultra graft covering extends beyond and covers a first open cell portion.



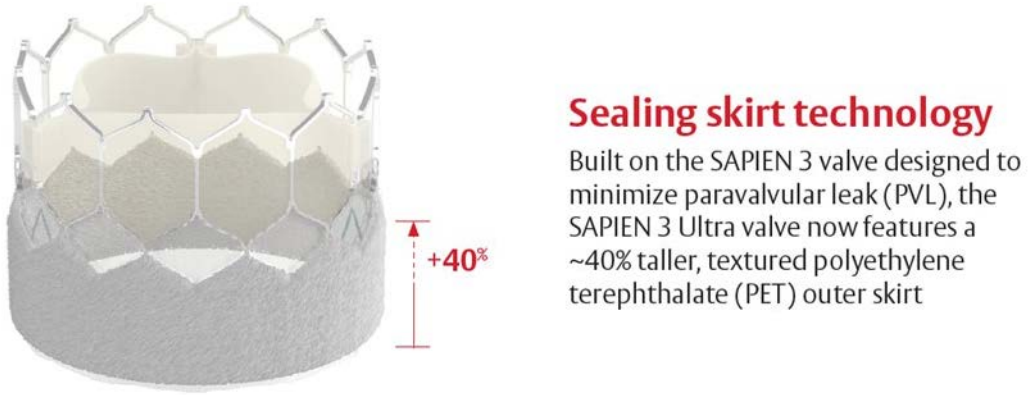
Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1-2, Ex. 46, https://edwardseducation.com/eacts2020/documents/PP--EU-0118%20v1.0%20S3%20Ultra%20on%20Commander%20Implanter%20Brochure.pdf

79. On information and belief, the outer frame is secured to the graft covering by a plurality of stitches at both ends of the graft covering.



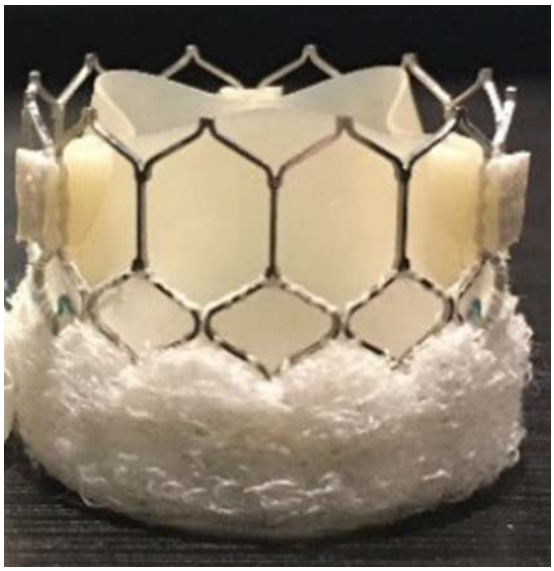
Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 2.

80. On information and belief, the Sapien 3 Ultra includes an external sealing skirt for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks.



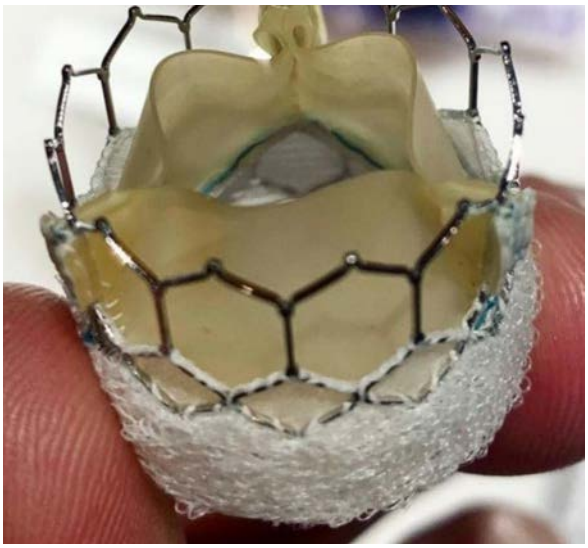
Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 2.

81. On information and belief, the Sapien 3 Ultra sealing skirt includes a plurality of outwardly extending non-metallic fibers that extend out from the outer frame to form the sealing material. On information and belief, the sealing material is attached to and extends over at least a portion of the outer frame.



Sapien 3 Ultra image by William Suh, MD at Ex. 7, https://twitter.com/willsuh76/status/1280708440734617600/photo/1.

82. On information and belief, the Sapien 3 Ultra further has a second portion of non-metallic fibers carried by the outer frame that are configured to form a second sealing interface against the outer frame when expanded.

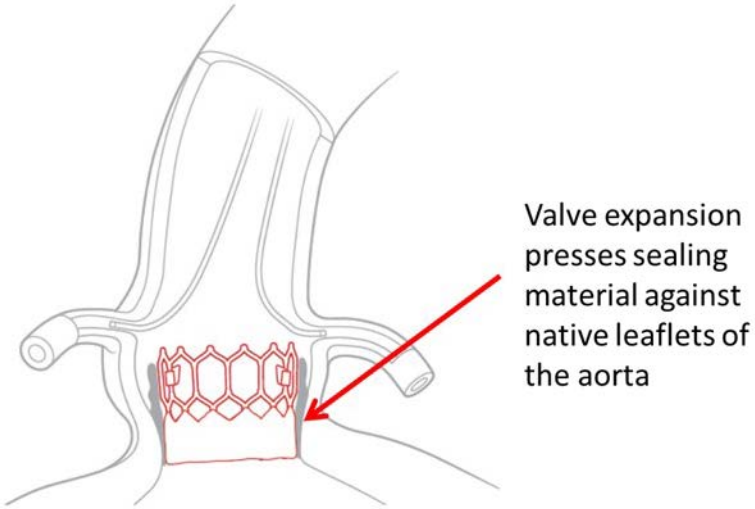


Ex. 29, https://www.instagram.com/p/BysjboFBLiG/.

83. On information and belief, the Sapien 3 Ultra is balloon expandable with a radially compressed orientation and a radially expanded orientation.

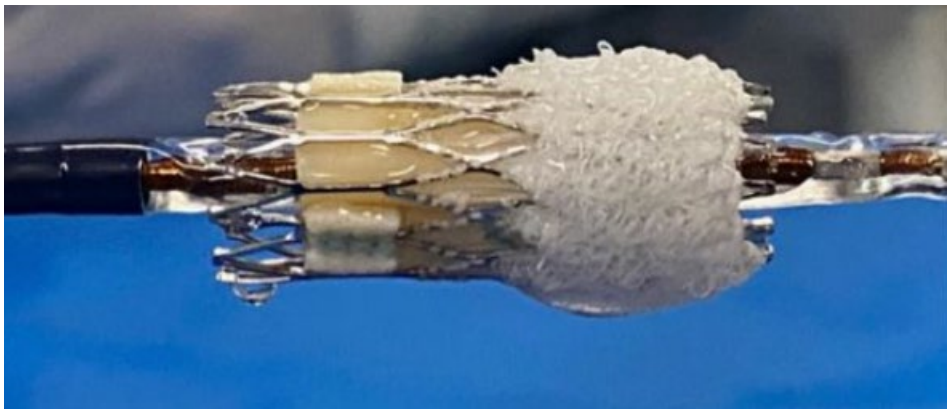
Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), Ex. 47, http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf; Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1 (annotation added).

84. On information and belief, expansion of the valve assembly presses the sealing material against the annulus and native leaflets of the aorta of the patient.



Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 4 (annotation added).

85. On information and belief, the Sapien 3 Ultra includes an outer frame where an end of the most proximal apices of the outer frame on the inflow side extend more proximally than a proximal end of the outer seal such that the end of the most proximal apices of the outer frame are uncovered by the outer seal and the graft covering.



Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (last accessed June 28, 2021).

86. On information and belief, Edwards designed, intends, and instructs doctors and other medical professional to use the Sapien 3 Ultra in TAVR procedures whereby a doctor or other medical professional: (1) endovascularly positions a guide wire through the aortic valve of a patient; (2) endovascularly positions the Sapien 3 Ultra transcatheter aortic valve assembly through the aortic valve of the patient, such that the sealing material fibers are in overlapping radial alignment with native valve leaflets of the patient; and (3) inflates a balloon assembly to expand the Sapien 3 Ultra transcatheter aortic valve assembly from a radially compressed orientation into a radially expanded orientation to seal against the native valve leaflets of the patient. Ex. 37, https://www.youtube.com/watch?v=o3whx7CdM3I; Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf.

87. On information and belief, when used or tested, Sapien 3 Ultra, and any other Edwards products that operate in substantially the same manner, either alone or in combination, directly infringe at least one claim of each of the Patents-in-Suit.

88. On information and belief, the Sapien 3 Ultra is designed and sold to be used in TAVR procedures in a specific way, as directed by the instructions for use provided with Sapien 3 Ultra and in promotion and training materials concerning Sapien 3 Ultra. *See, e.g.*, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf. Edwards manuals and its promotion and training materials provide specific instructions and guidance for using Sapien 3 Ultra in a way that infringes at least one claim of each of the Patents-in-Suit, and they do not contemplate any non-infringing uses.

GENERAL ALLEGATIONS RELATED TO INFRINGEMENT

89. Edwards has infringed and continues to directly and indirectly infringe at least one claim of each of the Patents-in-Suit by engaging in acts constituting infringement under 35 U.S.C.

§ 271(a), (b), (c) and/or (f), including but not limited to one or more of making, using, selling, offering for sale, importing, exporting the Accused Products, and inducing and contributing to infringement by others, in this District and elsewhere in the United States.

90. As a result of Edwards's infringement, AI has suffered and will continue to suffer harm in the form of damages. As a result of Edwards's misappropriations of Dr. Shahriari's inventions, AI was effectively precluded from bringing its TAVR device to market and selling its TAVR business. AI seeks damages for infringing acts beginning as early as six years prior to the filing of this Original Complaint.

91. On information and belief, Edwards had actual or constructive knowledge and notice of infringement as to each of the Patents-in-Suit. Edwards and its senior employees had direct communications with AI and Dr. Shahriari regarding Dr. Shahriari's inventions and the AI patents. Edwards also had knowledge of AI's patents and applications, including at least the AI '132 Application, which was cited during prosecution of Edwards's '651 Application. As such, Edwards knew, should have known, or was willfully blind as to the existence of the Patents-in-Suit at the time of Edwards's infringing acts.

92. On information and belief, Edwards's infringement of the Patents-in-Suit has been, and continues to be, willful because Edwards has committed and continues to commit acts of infringement even though Edwards knew or should have known that its actions constituted an unjustifiably high risk of infringement. Based on Edwards's interactions with Dr. Shahriari in the 2017 timeframe and thereafter, Edwards was aware or should have been aware of Dr. Shahriari's inventions related to TAVR and the use of an outer seal comprised of radially extending fibers. Despite such knowledge, Edwards incorporated Dr. Shahriari's TAVR inventions in and released

to market its Sapien 3 Ultra device. Edwards subsequently ignored communications from Dr. Shahriari or from others on Dr. Shahriari's behalf.

93. Further, prior to filing suit, Aortic Innovations contacted Edwards in a good faith effort to discuss Edwards's potential licensing of the AI patent portfolio. Specifically, on July 19, 2021, Dr. Shahriari sent an email to Mr. Bobo and Keith Newburry (Edwards's Vice President, Chief Intellectual Property Counsel) expressly informing them of Edwards's practice of the AI's portfolio including the Patents-in-Suit and related patents in relation to the Sapien 3 Ultra (as well as Edwards's practice of AI's mitral valve patents in relation to the Sapien M3) and requesting the opportunity to discuss a potential license. Ex. 22. On information and belief, after receiving notice, Edwards has not ceased its practice of the Patents-in-Suit.

94. Mr. Bobo responded to Dr. Shahriari on July 20, 2021 stating: "Thanks for the email and additional details, let me get to the team and take a look and we should be able to talk once we've taken a look. I've copied my admin Greta who can help with a followup time in early August." Ex. 49.

95. Instead of offering dates for a discussion in early August as Mr. Bobo suggested in the July 20, 2021 email, Mr. Bobo's assistant, Greta Cook, emailed Dr. Shahriari on July 21, 2021 with some proposed dates between August 30, 2021 and November 6, 2021. Ex. 50.

96. Upon information and belief, Edward's proffered dates for a discussion between Dr. Shahrari and Mr. Bobo between August 30, 2021 and November 6, 2021 instead of in "early August" as originally proposed by Mr. Bobo was intended to delay discussions between the Parties.

97. Despite Edwards's apparent attempts to postpone potential licensing discussions, Dr. Shahriari, continuing to want to reach an amicable resolution with Edwards, approached Seth

Damergy of UBS, an investment banker that had previously worked with Dr. Shahriari in connection with the sale of Ascyrus, to reach out to Mr. Bobo. Dr. Shahriari informed Mr. Bobo of this via an email sent on July 26, 2021 in which Dr. Shahriari wrote "Thank you both for the follow up. We have engaged Seth Damergy and the UBS team that worked with us on the sale of Ascyrus to assist here and he and his team will reach out to your assistant to help coordinate a call and discuss next steps. We look forward to our future discussions and the opportunity to work together." Ex. 51.

98. AI's representatives continued to correspond with Edwards, who implied that they were working towards a resolution of the dispute.

99. On September 10, 2021, Edwards filed an Inter Partes Review ("IPR") against AI's U.S. Patent No. 10,792,172 ("'172 Patent")—one of AI's patents identified in the July 19, 2021 email Dr. Shahriari sent to Edwards. *See* Ex. 22.

100. Despite the offer by Dr. Shahriari to reach an amicable resolution, Edwards did not make itself available to have a discussion with Dr. Shahriari until September 15, 2021—5 days after filing an IPR against the '172 Patent. But, instead of discussing a potential license of Dr. Sharhriari's patents in good faith, Mr. Bobo informed Dr. Shahriari that he was "insulted" by Dr. Shahriari's patents. Additionally, Mr. Westhart informed Dr. Shahriari that Edwards would seek to tie up Aortic Innovations in litigation for years.

101. In light of Edwards's knowledge of Dr. Shahriari's inventions, the Patents-in-Suit, its continued infringement, and its lack of good faith in the potential licensing discussions during the months leading up to this suit, Edwards's conduct has been egregious.

102. As demonstrated by the foregoing, Edwards's infringement of the Patents-in-Suit has been, and continues to be, without permission, consent, authorization, or license. As a result, Edwards's conduct was and is willful and egregious.

COUNT I: INFRINGEMENT OF THE '538 PATENT

103. AI incorporates by reference the preceding paragraphs as though fully set forth herein.

104. Edwards infringes, contributes to the infringement of, and/or induces infringement of the '538 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '538 Patent.

105. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '538 Patent. Edwards makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the '538 Patent.

106. For example, Claim 1 of the '538 Patent is reproduced below:

> 1. A method of implanting a transcatheter aortic valve assembly, comprising:
>
> endovascularly positioning a guide wire through the aortic valve of a patient;
>
> endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient, wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation,
>
> wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration,
>
> wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially

inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame,

wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame,

wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient;

inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation,

wherein the fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly,

wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.

107. As a non-limiting example, Sapien 3 Ultra is used according to a method of implanting a transcatheter aortic valve assembly. On information and belief, the Sapien 3 Ultra is used according to a method which includes endovascularly positioning a guide wire through the aortic valve of a patient.

108. On information and belief, the Sapien 3 Ultra is used according to a method which includes endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient.

109. On information and belief, the Sapien 3 Ultra transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation.

110. On information and belief, the Sapien 3 Ultra transcatheter aortic valve assembly includes an outer frame that is formed from a metallic material and defines an open cell configuration.

111. On information and belief, the Sapien 3 Ultra transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets.

112. On information and belief, the Sapien 3 Ultra inner frame includes a cylindrically extending graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.

113. On information and belief, the Sapien 3 Ultra outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame.

114. On information and belief, the Sapien 3 Ultra transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame.

115. On information and belief, the Sapien 3 Ultra transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient.

116. On information and belief, the Sapien 3 Ultra is used according to a method which includes inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation.

117. On information and belief, the Sapien 3 Ultra fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly.

118. On information and belief, the Sapien 3 Ultra fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.

119. Edwards also indirectly infringes claims of the ’538 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals,

doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards's affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the '538 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, and assist in the Sapien 3 Ultra TAVR procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '538 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '538 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '538 Patent.

120. Edwards also indirectly infringes claims of the '538 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '538 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '538 Patent, are not

staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the ’538 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the ’538 Patent and with intent, or willful blindness, that they cause the direct infringement of the ’538 Patent.

COUNT II: INFRINGEMENT OF THE ’846 PATENT

121. AI incorporates by reference the preceding paragraphs as though fully set forth herein.

122. Edwards infringes, contributes to the infringement of, and/or induces infringement of the ’846 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the ’846 Patent.

123. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the ’846 Patent. Edwards makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the ’846 Patent.

124. For example, Claim 1 of the ’846 Patent is reproduced below:

> 1. A valve assembly comprising:
>
> an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration;
>
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
>
> wherein the outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame;

an outer seal for preventing paravalvular leaks that begins at a proximal portion of the outer frame and extends over at least two rows of cells formed in the outer frame,

wherein the outer seal is attached to the outer frame,

wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame,

wherein the outer seal is free of an outer graft covering between the fibers and the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable and expansion of the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient.

125. As a non-limiting example, on information and belief, the Sapien 3 Ultra is a valve assembly. On information and belief, the Sapien 3 Ultra includes an outer frame that is formed from a metallic material and defines an open cell configuration.

126. On information and belief, the Sapien 3 Ultra includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets.

127. On information and belief, the Sapien 3 Ultra inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.

128. On information and belief, the Sapien 3 Ultra outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame.

129. On information and belief, the Sapien 3 Ultra includes an outer seal for preventing paravalvular leaks that begins at a proximal portion of the outer frame and extends over at least two rows of cells formed in the outer frame.

130. On information and belief, the Sapien 3 Ultra outer seal is attached to the outer frame.

131. On information and belief, the Sapien 3 Ultra outer seal is formed of outwardly extending fibers positioned externally to the outer frame.

132. On information and belief, the Sapien 3 Ultra outer seal is free of an outer graft covering between the fibers and the outer frame.

133. On information and belief, the Sapien 3 Ultra valve assembly has a radially compressed orientation and a radially expanded orientation.

134. On information and belief, the Sapien 3 Ultra valve assembly is balloon expandable and expansion of the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient.

135. Edwards also indirectly infringes claims of the ’846 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the ’846 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, and assist

in the Sapien 3 Ultra TAVR procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '846 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '846 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '846 Patent.

136. Edwards also indirectly infringes claims of the '846 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '846 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '846 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the '846 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '846 Patent and with intent, or willful blindness, that they cause the direct infringement of the '846 Patent.

COUNT III: INFRINGEMENT OF THE '236 PATENT

137. AI incorporates by reference the preceding paragraphs as though fully set forth herein.

138. Edwards infringes, contributes to the infringement of, and/or induces infringement of the ’236 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the ’236 Patent.

139. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the ’236 Patent. Edwards makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the ’236 Patent.

140. For example, Claim 1 of the ’236 Patent is reproduced below:

> 1. A transcatheter aortic valve assembly comprising:
>
> an outer frame formed from a metallic material;
>
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
>
> wherein the outer frame is secured to the inner graft covering by stitching;
>
> a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame,
>
> wherein the first portion of fibers is non-metallic; and
>
> a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst,
>
> wherein the second portion of fibers is non-metallic,
>
> wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

141. As a non-limiting example, on information and belief, the Sapien 3 Ultra is a transcatheter aortic valve assembly. On information and belief, the Sapien 3 Ultra includes an outer frame formed from a metallic material.

142. On information and belief, the Sapien 3 Ultra includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets.

143. On information and belief, the Sapien 3 Ultra inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.

144. On information and belief, the Sapien 3 Ultra outer frame is secured to the inner graft covering by stitching.

145. On information and belief, the Sapien 3 Ultra includes a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst.

146. On information and belief, the Sapien 3 Ultra first portion of fibers extend radially outwardly of the outer frame and is non-metallic.

147. On information and belief, the Sapien 3 Ultra includes a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst.

148. On information and belief, the Sapien 3 second portion of fibers is non-metallic.

149. On information and belief, the Sapien 3 Ultra first portion of fibers and the second portion of fibers are in overlapping radial alignment.

150. On information and belief, the Sapien 3 Ultra transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst.

151. On information and belief, the Sapien 3 Ultra valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame.

152. On information and belief, the Sapien 3 Ultra valve assembly has a radially compressed orientation and a radially expanded orientation.

153. On information and belief, the Sapien 3 Ultra valve assembly is balloon expandable to the radially expanded orientation and expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

154. On information and belief, the Sapien 3 Ultra valve assembly has a radially compressed orientation and a radially expanded orientation.

155. Edwards also indirectly infringes claims of the ’236 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals,

doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards's affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the '236 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, and assist in the Sapien 3 Ultra TAVR procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '236 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '236 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '236 Patent.

156. Edwards also indirectly infringes claims of the '236 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '236 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '236 Patent, are not

staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the ’236 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the ’236 Patent and with intent, or willful blindness, that they cause the direct infringement of the ’236 Patent.

COUNT IV: INFRINGEMENT OF THE ’735 PATENT

157. AI incorporates by reference the preceding paragraphs as though fully set forth herein.

158. Edwards infringes, contributes to the infringement of, and/or induces infringement of the ’735 Patent by making, using, selling, and/or offering for sale in, importing into, and/or exporting from the United States the Accused Products that are covered by one or more claims of the ’735 Patent.

159. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the ’735 Patent. Edwards makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the ’735 Patent.

160. For example, Claim 1 of the ’735 Patent is reproduced below:

> 1. An endovascular transcatheter valve assembly comprising:
>
> an outer frame,
>
> wherein the outer frame is formed from a metallic material and defines an open cell configuration,
>
> wherein the outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof,
>
> wherein the outer frame is formed by a plurality of struts that adjoin each other at the inflow end to form apices,

an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame,

an outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows of cells formed in the outer frame,

wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient,

wherein an end of the most proximal apices of the outer frame are uncovered by the outer seal and the graft covering,

wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal.

161. As a non-limiting example, on information and belief, Sapien 3 Ultra is an endovascular transcatheter valve assembly. On information and belief, Sapien 3 Ultra includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration, includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof, and is formed by a plurality of struts that adjoin each other at the inflow end to form apices.

162. On information and belief, Sapien 3 Ultra includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.

163. On information and belief, Sapien 3 Ultra the outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame.

164. On information and belief, Sapien 3 Ultra includes an outer seal for preventing paravalvular leaks that at least partially extends over at least the two most proximal rows of cells formed in the outer frame.

165. On information and belief, Sapien 3 Ultra outer seal is formed of outwardly extending fibers positioned externally to the outer frame.

166. On information and belief, the Sapien 3 Ultra valve assembly has a radially compressed orientation and a radially expanded orientation and is configured to press some of the fibers against native leaflets of the aorta of the patient.

167. On information and belief, the Sapien 3 Ultra end of the most proximal apices of the outer frame extend more proximally than a proximal end of the outer seal and are uncovered by the outer seal and the graft covering.

168. Edwards also indirectly infringes claims of the ’735 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the ’735 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its

employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, and assist in the Sapien 3 Ultra TAVR procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '735 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '735 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '735 Patent.

169. Edwards also indirectly infringes claims of the '735 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '735 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '735 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the '735 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '735 Patent and with intent, or willful blindness, that they cause the direct infringement of the '735 Patent.

DEMAND FOR JURY TRIAL

In accordance with Rule 38(b) of the Federal Rules of Civil Procedure and Local Rule 38.1, Plaintiff respectfully demands a jury trial of all issues triable to a jury.

PRAYER FOR RELIEF

WHEREFORE, AI respectfully requests that this Court enter judgment in its favor as follows and award AI the following relief:

1. an award of damages adequate to compensate AI for infringement of the Patents-in-Suit by Edwards, in an amount to be proven at trial, including supplemental post-verdict damages until such time as Edwards ceases its infringing conduct;

2. enhanced damages for willful infringement;

3. the costs of this action, as well as attorneys' fees as provided by 35 U.S.C. § 285;

4. pre-judgment and post-judgment interest at the maximum amount permitted by law;

5. all other relief, in law or equity, to which AI is entitled.

Dated: September 28, 2021

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Adam W. Poff

Adam W. Poff (No. 3990)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
apoff@ycst.com

MCKOOL SMITH, P.C.

John Campbell
John F. Garvish
303 Colorado, Suite 2100
Austin, Texas 78701
Telephone: (512) 692-8700
Facsimile: (512) 692-8744
jgarvish@McKoolSmith.com
jcampbell@McKoolSmith.com

Lauren Fornarotto
One Manhattan West
395 9th Avenue, 50th Floor
New York, New York 10001-8603
Telephone: (212) 402-9400
Facsimile: (212) 402-9444
lfornarotto@McKoolSmith.com

ATTORNEYS FOR PLAINTIFF AORTIC INNOVATIONS LLC