IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM; AND TISSUEGEN, INC.,	)	
Plaintiffs,	)	C.A. No. 1:18-cv-00392 (MN)
v.	)	
BOSTON SCIENTIFIC CORPORATION	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Board of Regents, The University of Texas System ("UTBOR") and TissueGen, Inc. ("TissueGen") (collectively, "Plaintiffs") file this their First Amended Complaint for Patent Infringement against defendant Boston Scientific Corporation ("BSX"). Plaintiffs' intent in filing this First Amended Complaint is to do the following:

- Remove Plaintiffs' allegations concerning U.S. Patent No. 7,033,603, given the parties' stipulation to dismissal of such allegations without prejudice (Dkt. 55) and the Court's July 27, 2020 Order (Dkt. 56) dismissing the same without prejudice.

- Particularly plead, by the deadline required by ¶ 2 of the Scheduling Order (Dkt. 47), Plaintiffs' allegations of BSX's direct, induced, and willful infringement of U.S. Patent No. 6,596,296 and Plaintiffs' entitlement to enhanced damages of at least 100 percent of the reasonable royalty to which Plaintiffs are entitled.

- Consistent with Plaintiffs' Original Complaint and their claim chart filed August 25, 2020 (Dkt. 61), make plain the accused products include all models of the SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System made, used, sold, or offered for sale in, or imported into, the United States during the period beginning November 20, 2011 and ending August 18, 2020, including (a) those products within the scope of FDA premarket approval application No. P150003 and supplement nos. P150003/S001 through P150003/S0062 thereto as listed on the following FDA website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150003; and (b) substantially similar products manufactured, used, or otherwise exploiting in clinical trials leading up to their commercial release, in the United States.

- State that Plaintiffs seek damages in the form of a reasonable royalty for infringement that occurred during the period November 20, 2011 to August 18, 2020, as well prejudgment interest and an enhancement of damages.

INTRODUCTION

A. THE PARTIES

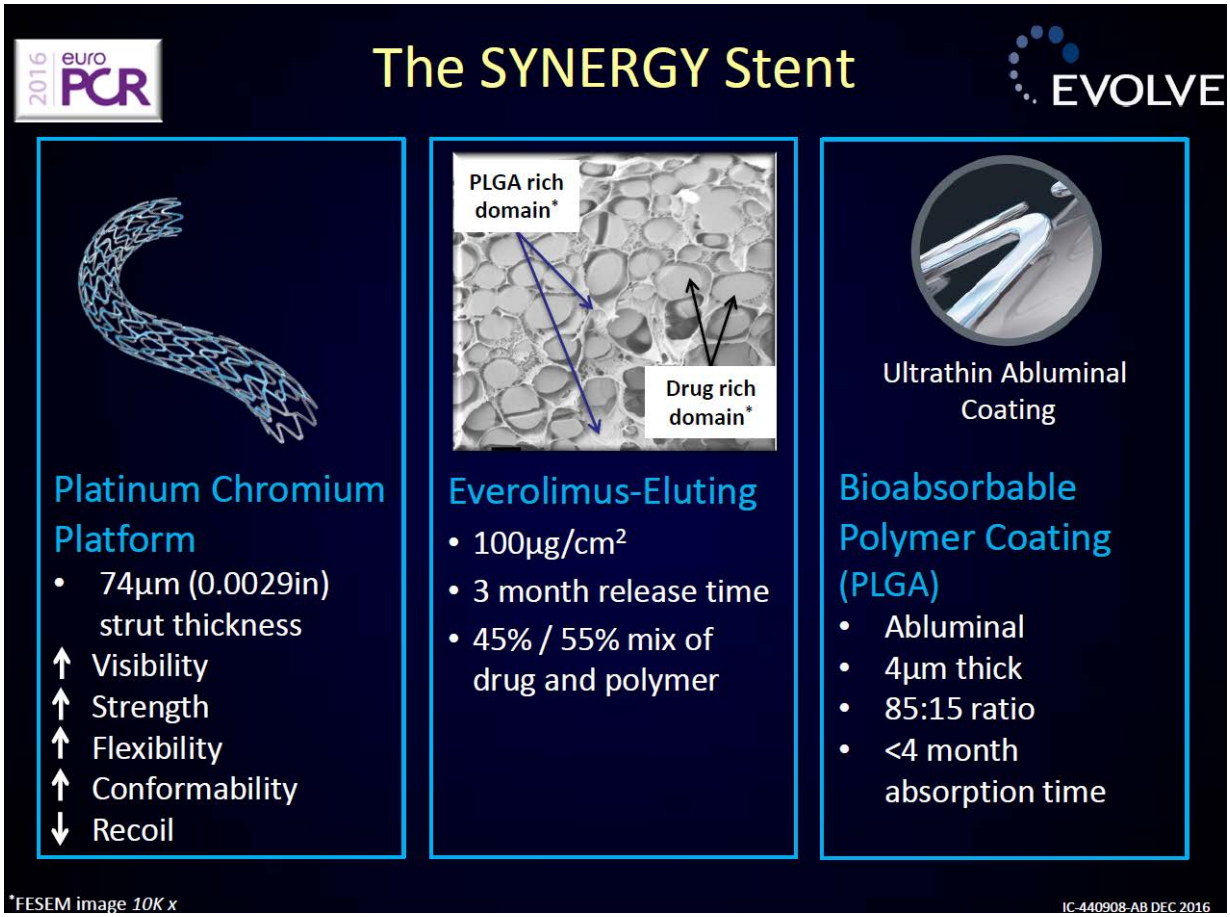
1. Board of Regents, The University of Texas System ("UTBOR"), an arm of the State of Texas, is the governing body for The University of Texas System ("UT System") and the assignee and exclusive owner of all right, title, and interest in U.S. Patent No. 6,596,296 ("'296 patent"), which arose out of research performed by Dr. Kevin Nelson and others in the late 1990s at The University of Texas at Arlington ("UTA"). Claim 1 of the '296 patent recites "A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents." UTA is one of UT System's fourteen institutions, which include eight academic institutions and six health institutions for medical research. UTBOR governs UT System through nine gubernatorially appointed regents and owns institutionally-generated intellectual property (IP) under Texas law. In turn, UTBOR protects, licenses, and at times enforces such IP for the public good and to encourage, promote, and foster innovation, economic development, and research by faculty, staff, students, and the private sector.

2. TissueGen Inc. ("TissueGen"), a Delaware corporation with its headquarters in Dallas, Texas, was the exclusive licensee of the '296 patent throughout its term. Dr. Nelson is now TissueGen's Chief Scientific Officer. He founded the company in July 2000 to improve the lives of real patients through the drug-releasing, bioabsorbable polymer fiber formats he pioneered through his research. Over the years, TissueGen has designed and developed such constructs for use in a range of medical applications, including stents for treating coronary artery disease and coated nitinol wire for treating atrial fibrillation.

3. Boston Scientific Corporation ("BSX"), a Delaware corporation with its world headquarters in Marlborough, Massachusetts, has, since as early as 2012, made, marketed,

distributed, and encouraged use of a family of coronary stents featuring a plurality of serially arranged serpentine rings made of a Platinum Chromium alloy (PtCr), each serpentine ring having, positioned on its abluminal (outside) surface, an ultrathin biodegradable polymer composed of everolimus-rich domains dispersed throughout an 85:15 PLGA [poly(DL-lactide-co-glycolide)] polymer matrix (collectively, "SYNERGY BP Stents"). In submissions to the U.S. Food and Drug Administration ("FDA"), BSX has represented that SYNERGY BP Stents are available in stent lengths of 8, 12, 16, 20, 24, 28, 32, 38, and 48 millimeters and stent diameters of 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50, and 5.00 millimeters. BSX has also represented that (a) SYNERGY BP Stents available in stent diameters of 2.25 to 2.75 millimeters have a stent strut thickness of 0.074 millimeters, which is 74 micrometers; (b) SYNERGY BP Stents available in stent diameters of 3.00 to 3.50 millimeters have a stent strut thickness of 0.079 millimeters, which is 79 micrometers; and (c) SYNERGY BP Stents available in stent diameters of 4.00 to 5.00 millimeters have a stent strut thickness of 0.081 millimeters, which is 81 micrometers.

4. The graphic labeled "The Synergy Stent" below in ¶ 4 of this First Amended Complaint reflects the fourth page of a 2016 presentation titled "Final five-year clinical outcomes in the EVOLVE trial: A randomised evaluation of a novel bioabsorbable polymer-coated, everolimus-eluting stent" (the "Presentation"), which is available on the BSX website through the the URL https://www.bostonscientific.com/content/dam/bostonscientific/Interventional Cardiology/general/clinical-spotlight/downloads/IC-440908-AB_Meredith_EVOLVE_FHU_5_year_for_CMO_Newsletter.pdf. The fourth page of the Presentation includes a field emission scanning electron microscopy (FESEM) image, at approximately 10,000 times magnification. The FESEM image was produced by or at the request of BSX. The FESEM image shows the abluminal polymer of SYNERGY BP Stents is made up of a drug rich domain dispersed as discrete regions throughout a PLGA rich domain.



5. BSX has at one or more times between November 20, 2011 and August 18, 2020 (the "Damages Period") marketed and distributed SYNERGY BP Stents in the United States under one or more of the trade names SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System, SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™), SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-The-Wire™), and SYNERGY™ XD Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™); under the UPNs identified by BSX in response to Plaintiffs' Interrogatory No. 2 and all supplemental responses thereto, including those UPNs listed the spreadsheet BSX produced in response, bearing bates number BSC-UTEX-00109825; and under authorization of FDA premarket approval (PMA) No. P150003 and supplements S001 to S062 thereto, including: S001, S002, S003, S004, S005, S006, S007, S008, S009, S010, S011, S012, S013, S014, S015, S016, S017, S018, S019, S020, S021, S022, S023, S024, S025, S026, S027, S028, S029, S030, S031, S032, S033, S034, S035, S036, S037, S038, S039, S040, S041, S042, S043, S044, S045, S046, S047, S048, S049, S050, S051, S052, S053, S055, S056, S057, S058, S059, S060, S061, S062. In connection with such activities, BSX has provided end users such as interventional cardiologists with instructions for using SYNERGY BP Stents in patients and encouraged use of the same in clinical trial settings.

6. BSX and its divisions, subsidiaries, and affiliates have at one or more times between November 20, 2011 and August 18, 2020 (the "Damages Period") maintained manufacturing and distribution operations concerning SYNERGY BP Stents in Ireland and in the United States, including in Minnesota and Massachusetts. At one or more times during the Damages Period, BSX has imported SYNERGY BP Stents into the United States. At one or more times during the Damages Period, BSX has sold or resold and offered to sell or resell SYNERGY BP Stents, in the

United States. At one or more times during the Damages Period, BSX has made SYNERGY BP Stents in the United States, including the preparation of and application of the abluminal ultrathin polymer to the SYNERGY BP Stents. On information and belief, at one or more times during the Damages Period, BSX has directed, contracted, and taken other steps to encourage one or more of its divisions, subsidiaries, and affiliates to sell, offer to sell, and import SYNERGY BP Stents to one or more buyers, in the United States. On information and belief, at one or more times during the Damages Period, BSX has directed, contracted, and taken other steps to encourage one or more of its divisions, subsidiaries, and affiliates to make SYNERGY BP Stents, in the United States, including application of the abluminal ultrathin polymer to the SYNERGY BP Stents.

B. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this dispute, and it has personal jurisdiction and venue over BSX. Subject matter jurisdiction exists pursuant to 28 U.S.C. §§ 1331 and 1338(a), as this action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. Personal jurisdiction over BSX exists at least because (a) BSX "admits that the United States District Court for the District of Delaware has jurisdiction over Boston Scientific" (Dkt. 40 at 2, ¶ 8) (BSX's Answer); (b) BSX did not raise a lack of personal jurisdiction defense in its Answer (*see id*. at 7); (c) BSX moved to transfer this action to this District; and (d) the exercise of jurisdiction comports with due process. BSX waived venue by moving to transfer to this District, participating in a scheduling conference, producing documents, and entering into stipulations with Plaintiffs, including a stipulated protective order. *Cf. Koninklijke Philips N.V. v. ASUSTek Comput. Inc.*, No. 1:15-cv-1125-GMS, 2017 WL 3055517, at *3 (D. Del. July 19, 2017) (Sleet, J.) (finding that defendants' conduct waived any venue defense where they "(1) participated in a scheduling conference; (2) conducted discovery; (3) entered into a stipulation and protective order with the plaintiff; and (4) moved the court to allow their out of state counsel to appear *pro hac vice*").

8. UTBOR's participation in this proceeding is not consent to the power of any court sitting outside of this District. UTBOR does not waive any attribute of sovereignty owing to the State of Texas and UTBOR's status as an arm of the same. UTBOR does not waive immunity to *inter partes* review, *ex parte* reexamination, or other post-grant proceedings at the USPTO. UTBOR does not waive immunity to any noncompulsory counterclaims, or to any other federal or state proceeding whatsoever, whether or not initiated by BSX.

C. HISTORY OF ANGIOPLASTY AND STENTING

9. Coronary artery disease is one of the leading causes of morbidity and mortality across the globe. The coronary arteries supply blood, oxygen, and nutrients to the heart. Coronary artery disease develops when the major blood vessels that supply the heart become damaged or clogged as a part of the atherosclerotic process, which includes plaque buildup and inflammation. Narrowing of these arteries decreases blood flow to the heart, while a complete blockage often causes heart attacks.

10. Marked narrowing in the coronary arteries is frequently treated with minimally invasive percutaneous coronary intervention ("PCI"). Today, PCI typically involves both balloon angioplasty (dilation of the narrowed arterial segment with a balloon catheter) and stent implantation, whereas angioplasty refers generally to any procedure that uses a balloon to open clogged heart arteries. Initially, in the early days, angioplasty was often performed without stent deployment, a procedure now known as "plain old balloon angioplasty" or balloon angioplasty. Balloon angioplasty resulted in inconsistent outcomes, however, due to myriad issues such as early elastic recoil (dynamic contraction of elastic compounds in the arterial wall occurring minutes after angioplasty), coronary dissection (a tear in the arterial wall from the balloon dilation resulting in a flap), and restenosis (re-narrowing of a coronary artery opened up with angioplasty due to exaggerated healing and scar formation). Coronary stents were developed to overcome the first

two limitations of balloon angioplasty by mechanically scaffolding the balloon-dilated artery, sealing the dissection flaps, and preventing late recoil.

11. UT System and its institutions have played a foundational role in the development and advancement of coronary stents since they were first introduced in the mid-1980s. In fact, in 1985, Julio Palmaz, a doctor at the University of Texas Health Science Center at San Antonio ("UTHSCSA") invented the first balloon-expandable, coronary bare-metal stent ("BMS"), for which he received a patent filed in 1985. Dr. Palmaz's pioneering coronary stent technology was later bought by Johnson & Johnson, and in 1987, the Palmaz-Schatz® (Johnson & Johnson) stent became the first FDA-approved stent in the USA. The Palmaz-Schatz® was one of the most studied and widely used stents throughout the 1990s. As studies confirmed the benefits of Palmaz-Schatz® stent deployment over balloon angioplasty, bare metal stent deployment became the standard of care in PCI, resulting in industry-wide patent infringement. In fact, nearly two decades later, BSX agreed to pay $716 million in cash for alleged infringement relating to Dr. Palmaz's invention. In its Form 10-K Annual Report submitted to the SEC for the fiscal year ended December 31, 2009, BSX discloses "payment of $716 million to Johnson & Johnson" in several places. This payment was to settle patent disputes with Johnson & Johnson concerning Dr. Palmaz's invention.

12. Though bare metal stent deployment marked an improvement over balloon angioplasty, bare metal stents had their own set of issues, including a high risk of in-stent restenosis ("ISR"), an event associated with significant morbidity and mortality. Investigators reported an exaggerated incidence of proliferation and migration of vascular smooth muscle cells ("VSMC") within the lumen circumscribed by the deployed bare metal stent as part of the healing process leading to re-stenosis (re-narrowing) of the artery. Proliferation and migration of vascular smooth

muscle cells were associated with an increased risk of in-stent restenosis. Reducing in-stent restenosis risk by adding a drug to the stent that would reduce proliferation of vascular smooth muscle cells is a key reason for drug-eluting stents ("DES").

13. Outside of UT System, from the late 1990s and throughout the better part of the first decade of this century, first and second generation drug eluting stents were designed to enclose bare metal stent scaffolds in a polymer skin composed of anti-proliferation compounds mixed with permanent polymers. Throughout this time, industry believed polymer degradation led to in-stent restenosis, as degradation would expose arterial tissue to bare metal stent scaffolding over time. For this and other reasons, BSX prioritized development of, and paid hundreds of millions of dollars to acquire rights in, drug-eluting stent technologies that delivered anti-proliferation compounds from permanent polymer conformally covering the entirety of an underlying bare metal stent scaffold like a skin.

14. For example, the first drug-eluting stent offered commercially by BSX in the United States was BSX's TAXUS Express2 everolimus-eluting stent. This stent became FDA approved in March of 2004 under FDA premarket approval (PMA) No. P030025. A few years later, in or about 2006, BSX paid $540 million dollars to acquire rights to Guidant's everolimus-based drug-eluting stent technology which BSX would share with Abbott Vascular. In July of 2008, under premarket approval (PMA) No. P070015, the FDA approved Abbott Vascular's PROMUS™ everolimus-eluting stent, which BSX then added to its own portfolio under the PROMUS name.

15. The TAXUS Express2 and PROMUS shared a similar design in that each delivered an anti-proliferation compound from a permanent polymer conformally covering the entire surface of an underlying bare metal stent scaffold like a skin.

16. The Summary of Safety And Effectiveness Data (SSED) maintained by the FDA

for the medical device approved under PMA No. P030025 accurately describes the device and drug components of the medical device approved under PMA No. P030025. This SSED is available through the URL https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030025B.pdf. Among other things, in § V.B, this SSED states "The drug component of the TAXUS Express2 Paclitaxel-eluting Coronary Stent System (referred to as the TAXUS Express Stent) consists of paclitaxel (the active ingredient) and Translute™ polymer carrier (the inactive ingredient)" and "The drug/polymer coating is adhered to the entire surface (i.e., luminal and abluminal) of the stent."

17. The Summary of Safety And Effectiveness Data (SSED) maintained by the FDA for the medical device approved under PMA No. P070015 accurately describes the device and drug components of the medical device approved under PMA No. P070015. This SSED is available through the URL https://www.accessdata.fda.gov/cdrh_docs/pdf7/P070015B.pdf. This SSED relates to the XIENCE™ V Everolimus Eluting Coronary Stent System (XIENCE V stent), which was also distributed as the PROMUS Over-the-Wire (OTW) Everolimus Eluting Coronary Stent System. Among other things, in § V.B, this SSED states "The XIENCE V Everolimus Eluting Coronary Stent (XIENCE V stent) is coated with everolimus (active ingredient), embedded in a non-erodible polymer (inactive ingredient)" and "The drug matrix copolymer is mixed with everolimus (83%/17% w/w polymer/everolimus ratio) and applied to the entire PBMA coated stent surface."

18. Everolimus is a derivative of sirolimus, a natural macrocyclic lactone with immunosuppressant and anti-angiogenic properties. Everolimus is a macrocyclic lactone that is related to rapamycin by substituting a 2-hydroxyethyl ether for the hydroxy group attached to the cyclohexyl moiety. Everolimus is a proliferation signal inhibitor with immunosuppressant and

antineoplastic properties. It has a role as an antineoplastic agent, an immunosuppressive agent, a mTOR inhibitor and an anticoronaviral agent. It is a primary alcohol, a secondary alcohol, an ether, a cyclic ketone, a cyclic acetal, and a macrolide lactam. It derives from a member of sirolimus.

19. Polyethylene-co-vinyl acetate ("PEVA") is a non-erodible polymer.

20. Poly n-butyl methacrylate ("PBMA") is a non-erodible polymer.

21. The polymer marketed under the tradename Translute™ is a non-erodible polymer.

22. PVDF-HFP is a non-erodible random copolymer.

23. Each of the polymers identified in ¶¶ 19-22 herein is a permanent polymer.

24. Thus, as of the calendar year ending December 31, 2009, neither BSX nor anyone else known to BSX at the time had developed or commercialized technology for controlled delivery of anti-proliferation compounds from an ultrathin biodegradable polymer fiber.

D. DR. NELSON'S DRUG-ELUTING FIBER INNOVATION

25. In 1996, Dr. Nelson was a rising member of the Biomedical Engineering faculty at UTA and less than a year removed from having earned his Ph.D. from a dual degree program offered through UTA and UT Southwestern Medical Center at Dallas ("UT Southwestern").

26. Though the industry believed otherwise, Dr. Nelson believed in the commercial viability of a drug eluting stent based on biodegradable polymer fibers capable of controlled release of sensitive therapeutics.[1] Dr. Nelson came up with the idea for his drug eluting stent innovation while investigating ways to deliver a virus to the arterial wall for the purpose of healing, not simply treating, damaged arteries. The hypothesis was that biologically active substances could be used to modify the arterial wall in a way that would prevent restenosis without requiring prolonged

[1] At the time, others in the field, such as BSX, were focusing on nondegradable microparticles. In fact, between 1998 and 2002, this was the very approach advocated by BSX, as reflected by its patent applications, including U.S. Patent App. No. 09/910,288, filed July 20, 2001, which issued as U.S. Patent No. 8,067,022 on November 29, 2011.

exposure of the wall to polymer material. Dr. Nelson started to work on a prototype. He began by creating fibers that could be coiled in a new stent configuration. He then created a thin film sheath from a polymer/virus solution and afterwards wrapped the sheath around the coiled fiber like a jelly roll. However, the sheath prevented the stent from expanding as desired, and its geometry and large surface area hindered the consistency of therapeutic dosing and distribution from one prototype to the next.

27. Dr. Nelson's solution, which he memorialized in his lab notebook on October 17, 1997, was inspired by his efforts to coil a fiber into a stent configuration, and by phase separation concepts he encountered while simultaneously investigating drug delivery to the inner ear: a fiber made up of an immiscible discontinuous drug-containing phase dispersed throughout a biodegradable polymer carrier phase. The unique technical characteristics of fibers (e.g., high aspect ratio, large surface area to volume ratio), together with phase separated therapeutics and polymer biodegradability, would enable tunable yet consistent therapeutic dosing, distribution, and release, as well as construction of almost any type of device from or in combination with fibers having any desired spatial and temporal drug release profile.

28. With his first master's students, Andres Romero-Sanchez and Paula Waggoner, Dr. Nelson succeeded in creating prototype fibers (often using Evan's blue die as a mock drug). Together with Drs. George Smith and Nadir Alikacem, Dr. Nelson tested his prototype fibers in animal models (e.g., rats and rabbits). Together, Drs. Nelson and Smith showed fascicle formation in regenerated nerves using fibers Dr. Nelson created. And with Dr. Alikacem, Dr. Nelson demonstrated the ability to load small pharmaceutical agents into a fiber to help stem the blindness that results from diabetes. The success of these and numerous other experiments demonstrated the benefits of Dr. Nelson's technology and set him on a path to commercialization.

29. Thus, on July 24, 2000, with a $5,000 investment, Dr. Nelson founded TissueGen with the belief that real patients' lives could be dramatically improved if the technology could be practiced outside of the university research setting.

E. THE '296 PATENT

30. On August 4, 2000, Dr. Nelson and six co-inventors filed U.S. Patent Application No. 09/632,457, entitled "Drug Releasing Biodegradable Fiber Implant," which issued on July 22, 2003 as the '296 patent, and which claims priority to U.S. Provisional Patent App. No. 60/147,827, which was filed on August 6, 1999. A copy of the '296 patent is attached as Exhibit A to Plaintiffs' Original Complaint for Patent Infringement (Dkt. 1) and is incorporated herein by reference.

31. '296 patent claim 11 depends from claim 1, and fairly may be read as:

> A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents; [and] wherein said one or more therapeutic agents are selected from the group consisting of drugs, proteins, enzymes, growth factors, immunomodulators, compounds promoting angiogenesis, compounds inhibiting angiogenesis, anti-inflammatory compounds, antibiotics, cytokines, anti-coagulation agents, procoagulation agents, chemotactic agents, agents to promote apoptosis, agents to inhibit apoptosis, and mitogenic agents.

32. '296 patent claim 12 depends from claim 1, and fairly may be read as:

> A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents; [and] wherein said one or more therapeutic agents include a radioactive agent or a contrast agent for imaging studies.

33. '296 patent claim 17 depends from claim 16, which depends from claim 1, and fairly may be read as:

> A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the

> second phase comprises one or more therapeutic agents; wherein said biodegradable polymer is a single polymer, a co-polymer, or a mixture of polymers selected from the group consisting of polypeptides, polydepsipeptides, nylon copolyamides, aliphatic polyesters, polydihydropyrans, polyphosphazenes, poly(ortho ester), poly(cyano acrylates), polyanhydride, modified polysaccharides and modified proteins; [and] wherein said aliphatic polyesters are selected from the group consisting of poly(glycolic acid), poly(lactic acid), poly(alkylene succinates) poly(hydroxybutyrate), poly(butylene diglycolate), poly(epsilon-caprolactone) and copolymers, blends and mixtures thereof.

34. ’296 patent claim 26 depends from claim 1, and fairly may be read as:

> A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents; wherein said one or more therapeutic agents are released at varying rates over time from said fiber.

35. The ’296 patent includes drawings labeled “FIG. 1,” “FIG. 3a,” “FIG. 3b,” and “FIG. 4.” The ’296 patent includes a section titled “SUMMARY OF THE INVENTION” that begins in or about column 2, line 39, and ends in or about column 6, line 54. The ’296 patent includes a section titled “BRIEF DESCRIPTION OF THE DRAWINGS” that begins in or about column 6, line 56, and ends in or about column 8, line 14. The ’296 patent includes a section titled “DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS” that begins in or about column 8, line 15 and ends in or about column 26, line 20. Within the DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS section, the ’296 patent includes, among other things, (a) a subsection titled “Example 3 Fabrication of Polymer Fibers with Concentric Coatings” that begins in or about column 20, line 8, and ends in or about column 20, line 36; and (b) a subsection titled “Example 7 Preparation and Use of Polymer Stents” that begins in or about column 22, line 40 and ends in or about column 22, line 52.

36. The graphic that appears in this paragraph as FIG. 1 accurately depicts the substance of FIG. 1, as it appears on "Sheet 1 of 11" of the '296 patent. The graphic that appears in this paragraph as FIG. 3a accurately depicts the substance of FIG. 3a, as it appears on

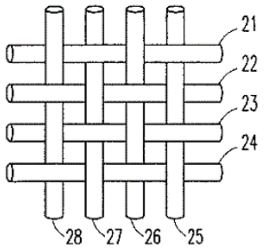


FIG. 1

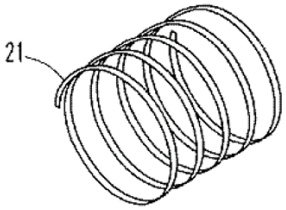


FIG. 3a

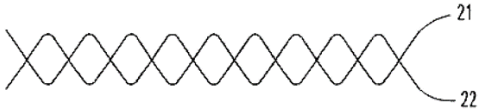


FIG. 3b

'296 patent "Sheet 1 of 11." The graphic that appears in this paragraph as FIG. 3b accurately depicts the substance of FIG. 3b, as it appears on '296 patent "Sheet 2 of 11."

37. Beginning in or about column 6, line 63, and ending in or about column 6, line 67, the '296 patent states: "FIG. 1: Shows fibers configured in a complex three-dimensional woven scaffolding with patterning. Each of the individual fibers may be loaded with one or more therapeutic agents. The numerals 21-27 denote fibers loaded with therapeutic agents."

38. Beginning in or about column 7, line 8, and ending in or about column 7, line 14, the '296 patent states: "FIG. 3A and FIG. 3B: Fibers can provide the body with short term mechanical support in such applications as stents. FIG. 3A illustrates that a single polymer fiber can maintain the lumen of any tubular body, such as arteries, veins, or ducts. FIG. 3B illustrates that multiple polymer fibers can maintain the lumen of tubular bodies. The numerals 21-25 denote fibers loaded with therapeutic agents."

39. Beginning in or about column 20, line 12, and ending in or about column 20, line 21, the '296 patent states: "In yet another fabrication embodiment, a pre-existing fiber is loaded through a spinneret and through the coagulation bath. The liquid polymer emulsion is added in a "T" or "Y" junction and coats the fiber before entering a coagulation bath. Thus concentric

coatings are applied to the fiber, with each coating having the ability to contain a different therapeutic agent(s) as shown in FIG. 4. The coating polymer may be the same or different from the core polymer. There may be molecules attached to the core fiber to increase the adhesion of the coating polymer."

40. Beginning in or about column 20, line 29, and ending in or about column 20, line 32, the '296 patent states: "In certain embodiments, the spinneret may have a non-circular shape, thereby forming fibers with any desired cross-sectional shape. This is true of the core fiber as well as the coating polymers."

41. Beginning in or about column 3, line 24, and ending in or about column 3, line 25, the '296 patent states: "Preferably, the diameter of the fibers will be from about 60 microns to about 80 microns."

42. Beginning in or about column 4, line 1, and ending in or about column 4, line 11, the '296 patent states: "For fibers that contain one or more therapeutic agents, the agent or agents may include a growth factor, an immunodulator [*sic*], a compound that promotes angiogenesis, a compound that inhibits angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a procoagulation agent, a chemotactic agent, an agents that promotes apoptosis, an agent that inhibits apoptosis, a mitogenic agent, a radioactive agent, a contrast agent for imaging studies, a viral vector, a polynucleotide, therapeutic genes, DNA, RNA, a polypeptide, a glycosaminoglycan, a carbohydrate, a glycoprotein."

43. Beginning in or about column 8, line 26, and ending in or about column 8, line 31, the '296 patent states: "The term therapeutic agent in this invention also includes radioactive materials used to help destroy harmful tissues such as tumors in the local area, or to inhibit growth of healthy tissues, such as in current stent applications; or markers to be used in imaging studies."

44. Beginning in or about column 22, line 43, and ending in or about column 22, line 47, the '296 patent states: "In another embodiment, fibers can be loaded with a drug of interest and used in stents or other medical devices where mechanical strength is required. The stents can be woven in such a manner as to have loaded fibers intermingled with unloaded fibers if needed for mechanical properties."

45. Beginning in or about column 22, line 48, and ending in or about column 22, line 51, the '296 patent states: "Fibers can also be used in conjunction with commercially available stents to deliver drugs at the placement site. In this case, the fibers would not provide any mechanical support, but would only serve as a drug delivery reservoir."

F. BSX'S INTERACTIONS WITH TISSUEGEN

46. BSX and TissueGen were not strangers before Plaintiffs filed this patent infringement action. BSX was aware of Dr. Nelson and his inventions before 2007.

47. On or about January 11, 2007, acting on behalf of BSX and authorized by Mr. Scott Bluni in prosecuting U.S. Patent Application No. 11/395964 to Strickler and Tenney (the "Strickler Application"), agents of BSX disclosed, to the USPTO, BSX's knowledge of (a) U.S. Patent number "6,596,296 B1" to "Nelson et al."; (b) U.S. Patent Publication number "2004/0028655 A1" to "Nelson et al."; and (c) U.S. Patent Publication number "2005/0208107 A1" to "Nelson et. al." The Strickler Application is titled "Medical Devices Containing Multi-Component Fibers," and is, among other things, directed to a stent with a fibrous layer over a metallic substrate. In column 22 of the '296 patent, between lines 40 and 52, under the heading "Example 7" and subheading "Preparation and Use of Polymer Fiber Stents," the '296 patent discloses, among other things, "[f]ibers can be loaded with a drug of interest and used in stents or other medical devices where mechanical strength is required" and "[f]ibers can also be used in conjunction with commercially available stents to deliver drugs at the placement site. In this case, the fibers would

not provide any mechanical support, but would only serve as a drug delivery reservoir."

48. In the 2006 to 2007 timeframe, Mr. Bluni served as, or held the titles of, Cardiovascular Chief Patent Counsel and Vice President at BSX. In or about March of 2006, he also served as, or held a title of, "Asst. Secretary" at Boston Scientific Scimed, Inc. Mr. Bluni signed a Power of Attorney dated March 7, 2006, which accompanied the Strickler Application when it was transmitted to the USPTO on or about March 31, 2006.

49. Beginning no later than about early 2007 and continuing through 2010, on information and belief, BSX was aware of, analyzed, and possessed the '296 patent and other patents sharing its disclosure. Boston Scientific Limited ("BSL") was an affiliate of BSX during the 2007 to 2010 time frame, and further, on information and belief, BSX and BSL were under common control.

50. On or about January 20, 2009, BSL received an International search report (the "Search Report") in connection with prosecution of International patent application No. PCT/US2007/007778. In addition to the '296 patent, the Search Report identifies, among other things, "examples 6-9" as "relevant passages" within a document cited as "WO 2004/098503 A (UNIV TEXAS [US]; NELSON KEVIN D [US]; CROW BRENT B [US]) 18 November 2004 (2004-11-18)." Example 7 of International Patent Publication No. WO 2004/098503 includes the subheading "Preparation and use of polymer fiber stents" and provides, among other things, "[f]ibers can be loaded with a drug of interest and used in stents or other medical devices where mechanical strength is required" and "[f]ibers can also be used in conjunction with commercially available stents to deliver drugs at the placement site. In this case, the fibers would not provide any mechanical support, but would only serve as a drug delivery reservoir."

51. On or about April 3, 2009, BSX submitted the Search Report and International

Patent Publication No. WO 2004/098503 to the USPTO in prosecution of the Strickler Application.

52. On or about September 15, 2009, in prosecuting the Strickler Application, BSX submitted remarks (the "Remarks") to the USPTO in order to overcome the examiner's rejections over references that included "Nelson et al (U.S. Patent Application Publication No. 2004/0028655) ("NELSON")." In the remarks, BSX asserted, among other things, "NELSON does not teach or suggest the use of a metallic substrate with a fibrous layer over the metallic substrate" and "NELSON does not teach or suggest any substrate for the fibers its uses since the fibers themselves are used alone."

53. Further, on or about October 16, 2008, Mary Beth Moynihan and Kevin Ballinger met with Dr. Nelson during the 2008 Transcatheter Cardiovascular Therapeutics ("TCT") Symposium. In or around that time, Ms. Moynihan held, or held herself out to hold, the title "Vice President, New Business Development" in "Interventional Cardiology" at BSX. In or around the same time, Mr. Ballinger held, or held himself out to hold, the title "Vice President, R&D and Program Management" at BSX. In the 2008 to 2009 timeframe, both Ms. Moynihan and Mr. Ballinger had, and was authorized to send and receive information from, a work email address that included the domain "bsci.com."

54. During their October 2008 meeting, Dr. Nelson introduced TissueGen and its biodegradable drug-eluting peripheral stent technology to Ms. Moynihan and Mr. Ballinger. In addition, Dr. Nelson gauged BSX's interest in participating as an investor in TissueGen's upcoming Series A round of investment. Thus, in October 2008, both Ms. Moynihan and Mr. Ballinger received directly from Dr. Nelson at least an overview of TissueGen's technology and plans concerning outside investment. When the meeting ended, Ms. Moynihan and/or Mr. Ballinger indicated that they would take time to consider TissueGen's technology and

investment request.

55. Ms. Moynihan and Dr. Nelson remained in touch between November 2008 and April 2009. For example, on or about November 12, 2008, Ms. Moynihan emailed Dr. Nelson from her work email address, stating: "It was nice to meet you at TCT and receive an overview of your technology and plans. As we mentioned at the end of the meeting, Kevin and I wanted to take some time to consider your technology and request. As we mentioned during the meeting, BSC has decided not to make passive equity investments in early stage technologies. While we think that your technology and ideas are interesting, TissueGen is not currently at a stage in which it makes sense for BSC to invest."

56. On or about April 17, 2009, Ms. Moynihan received, through her work email address, a message from Dr. Nelson in which, among other things, he offered to send Ms. Moynihan a PowerPoint presentation containing "more information" about TissueGen's stent design and its proprietary/patented phase-separated modified wet extrusion process to combine biodegradable polymers with therapeutic agents.

57. On or about April 23, 2009, Ms. Moynihan asked Dr. Nelson to forward the "additional information" he had referenced in his April 17, 2009 email to her. On information and belief, Ms. Moynihan received the requested information.

58. Ms. Moynihan was aware of '296 patent by the end of April 2010.

59. Mr. Ballinger was aware of '296 patent by the end of April 2010.

60. Multiple employees, officers, or directors of BSX were aware of the '296 patent by the end of April 2010.

61. Ms. Moynihan and other current and former employees of BSX know how BSX went about evaluating TissueGen's technology, the extent to which BSX analyzed the '296 patent

and other patents relating to TissueGen's technology, and what BSX did or did not do to determine whether, without infringing one or more claims of the '296 patent, BSX could or could not make, use, or sell, or encourage others to make, use, or sell, coronary stents that delivered therapeutics from ultrathin biodegradable polymers attached to the abluminal surface of the stent struts.

62. During the April 30, 2010 to October 2, 2015 time frame, Ms. Moynihan held, or held herself out to hold, one or both of the following positions at BSX: "Vice President, Corporate Strategy and Research" and "Senior Vice President, Enterprise Strategy and Marketing." During this same time frame, April 30, 2010 to October 2, 2015, Mr. Ballinger held, or held himself out to hold, the following position at BSX: "EVP and Global President, Interventional Cardiology."

G. THE SYNERGY BP STENTS

63. In or around January 2015, BSX submitted to the FDA a premarket approval application seeking approval to market SYNERGY BP Stents. BSX amended its application on January 20, March 10, March 26, April 15, June 17, July 7, and July 22, 2015. On or about October 2, 2015, the FDA approved BSX's premarket approval application seeking approval to market SYNERGY BP Stents.

64. BSX also manufactured SYNERGY BP Stents in the United States for a period of time before October 2, 2015. For example, with BSX's approval, in or about September of 2014, several BSX employees authored a paper titled "The SYNERGY Biodegradable Polymer Everolimus Eluting Coronary Stent: Porcine Vascular Compatibility and Polymer Safety Study" (the "Study"). In the abstract, the Study states "SYNERGY is a novel platinum chromium alloy stent that delivers abluminal everolimus from an ultrathin poly-lactide-co-glycide (PLGA) biodegradable polymer." In describing the study methods, the Study states "Three SYNERGY stents were used: nominal SYNERGY manufactured in either Maple Grove, MN or Galway, Ireland or the SYNERGY FHU stent."

65. BSX has represented the following to third parties: "SYNERGY BP Stents: The SYNERGY BP Stent was the first FDA-approved drug-eluting stent with abluminal bioabsorbable polymer coating available in the U.S. It was designed to address the challenges associated with permanent polymer stents such as inflammation, neoatherosclerosis and late stent thrombosis."

66. BSX has represented the following to third parties: "The SYNERGY and XYNERGY [*sic*] stents are comprised of a Platinum Chromium Alloy (PtCr). Similar to other metallic stents manufactured by BSC, the stent component is laser cut into a specific geometric pattern which consists of serpentine rings connected by links that are highly polished to a uniform rounded surface."

67. Regarding the SYNERGY BP Stents, BSX has represented the following to third parties: "Three (3) separate stent models were designed in specific size ranges. A stent model is defined as a variation of a specific geometry pattern designed for various vessel diameters. The three models are defined below:

- Small Vessel (SV): 2.25 mm, 2.50 mm, and 2.75 mm
- Workhorse (WH): 3.00 mm and 3.50 mm
- Large Vessel (LV): 4.00 mm, 4.50 and 5.00mm[.]"

68. BSX has described the struts making up each serpentine ring of the SYNERGY BP Stents as "ultra-thin."

69. The strut thickness for the Small Vessel model of the SYNERGY BP Stents is seventy-four micrometers (74 µm) (0.0029 inches).

70. The strut thickness for the Workhorse model of the SYNERGY BP Stents is seventy-nine micrometers (79 µm) (0.0031 inches).

71. The strut thickness for the Large Vessel model of the SYNERGY BP Stents is eighty-one micrometers (81 µm) (0.0032 inches).

72. BSX has represented the following to third parties: "SYNERGY and SYNERGY

XD are abluminally coated with a bioabsorbable coating. The coating consists of bioabsorbable PLGA polymer and everolimus. The PLGA polymer provides controlled and sustained release of available everolimus through the intended time frame, during which the polymer is reabsorbed into the body."

73. BSX has represented the following to third parties: "The SYNERGY BP Stent provides synchronous drug elution and polymer absorption; the polymer is absorbed shortly after the drug elution is complete at 3-months, providing rapid healing and freedom from long-term polymer exposure."

74. BSX has represented the following to third parties: "On a cellular level, everolimus inhibits, in a reversible manner, growth factor-stimulated cell proliferation. On a molecular level, everolimus forms a complex with the cytoplasmic protein FKBP-12. In the presence of everolimus, the growth factor stimulated phosphorylation of p70 S6 kinase and 4E-BP1 is inhibited. The latter proteins are key proteins involved in the initiation of protein synthesis. Since phosphorylation of both p70 S6 kinase and 4E-BP1 is under the control of FRAP (FKBP-12-rapamycin associated protein, also called mTOR, mammalian target of rapamycin) this finding suggests that, the everolimus-FKBP-12 complex binds to and thus interferes with the function of FRAP. FRAP is a key regulatory protein which governs cell metabolism, growth and proliferation. Disabling FRAP function explains the cell cycle arrest at the late G1 stage caused by everolimus."

H. BSX'S POST-SUIT ACTIONS

75. On or about November 20, 2018, one year after TissueGen filed suit, BSX waived its right to challenge the validity of the '296 patent through the *inter partes* review process.

76. On May 11, 2020, BSX filed its answer (Dkt. 40) to Plaintiffs' Original Complaint. BSX's answer (Dkt. 40) omits a counterclaim for invalidity of the '296 patent and omits a counterclaim for noninfringement of the '296 patent.

77. Nonetheless, since this action was filed in November 2017, BSX continued to import and sell SYNERGY BP Stents into and in the United States and to direct or contract one or more of its divisions, subsidiaries, and affiliates to sell and ship SYNERGY BP Stents to buyers, in the United States.

COUNT I: DIRECT INFRINGEMENT

78. Plaintiffs repeat and re-allege each and every allegation of the prior paragraphs as though set forth fully herein.

79. Plaintiffs allege the SYNERGY BP Stents practice '296 patent claims 1, 11, 12, 17, and 26. Plaintiffs adopt, and incorporate by reference, as if fully stated herein, Plaintiffs' claim chart filed at ECF pages 4-9 of Dkt. 61, which describes and demonstrates how the accused SYNERGY BP Stents practice '296 patent claims 1, 11, 12, 17, and 26.

80. As set forth in row (11.0) on ECF page 4 of Dkt. 61, literally, the SYNERGY BP Stents infringe each of '296 patent claims 1 and 11 because: (a) each such stent includes at least one "biodegradable polymer fiber" in the form of an ultrathin bioabsorbable 85:15 PLGA polymer positioned on the outside surface (side in contact with the coronary artery wall) of any one serpentine ring of the stent; (b) such ultrathin bioabsorbable polymer is composed of a "first phase," in the form of an 85:15 PLGA polymer-rich matrix, that is not miscible with a "second phase," in the form of discrete, everolimus-rich domains that are dispersed throughout the 85:15 PLGA polymer-rich matrix; and (c) everolimus is a "therapeutic agent," "immunomodulator," and "compound inhibiting angiogenesis" in that it has immunosuppressant properties, has anti-angiogenic properties, and is included in a locally therapeutic amount.

81. As set forth in row (12.0) on ECF page 5 of Dkt. 61, literally or under the doctrine of equivalents, the SYNERGY BP Stents infringe '296 patent claim 12 because: (a) each such stent includes at least one "biodegradable polymer fiber" in the form of an ultrathin bioabsorbable

85:15 PLGA polymer positioned on the outside surface (side in contact with the coronary artery wall) of any one serpentine ring of the stent; (b) such ultrathin bioabsorbable polymer is composed of a "first phase," in the form of an 85:15 PLGA polymer-rich matrix, that is not miscible with a "second phase," in the form of discrete, everolimus-rich domains that are dispersed throughout the 85:15 PLGA polymer-rich matrix; (c) everolimus is a "therapeutic agent," "immunomodulator," and "compound inhibiting angiogenesis" in that it has immunosuppressant properties, has anti-angiogenic properties, and is included in a locally therapeutic amount; and, (d) a second phase containing "everolimus" is, or is an insubstantial change from, a second phase containing the recited "a radioactive agent" in that (i) everolimus is a radiosensitizer, (ii) everolimus has been shown to have a synergistic effect with radiation in killing tumors and inhibiting cell growth, (iii) and, notwithstanding the foregoing, like the "radioactive materials" contemplated in or about column 8, line 26, through column 8, line 30, of the '296 patent, everolimus is among "materials used to help destroy harmful tissues such as tumors in the local area, or to inhibit growth of healthy tissues."

82. As set forth in row (17.0) on ECF page 6 of Dkt. 61, literally, the SYNERGY BP Stents infringe '296 patent claim 17 because: (a) each such stent includes at least one "biodegradable polymer fiber" in the form of an ultrathin bioabsorbable 85:15 PLGA polymer positioned on the outside surface (side in contact with the coronary artery wall) of any one serpentine ring of the stent; (b) such ultrathin bioabsorbable polymer is composed of a "first phase," in the form of an 85:15 PLGA polymer-rich matrix, that is not miscible with a "second phase," in the form of discrete, everolimus-rich domains that are dispersed throughout the 85:15 PLGA polymer-rich matrix; (c) everolimus is a "therapeutic agent," "immunomodulator," and "compound inhibiting angiogenesis" in that it has immunosuppressant properties, has anti-

angiogenic properties, and is included in a locally therapeutic amount; and (d) 85:15 PLGA is an aliphatic polyester copolymer of poly(glycolic acid) and poly(lactic acid).

83. As set forth in row (26.0) on ECF page 7 of Dkt. 61, literally, the SYNERGY BP Stents infringe '296 patent claim 26 because: (a) each such stent includes at least one "biodegradable polymer fiber" in the form of an ultrathin bioabsorbable 85:15 PLGA polymer positioned on the outside surface (side in contact with the coronary artery wall) of any one serpentine ring of the stent; (b) such ultrathin bioabsorbable polymer is composed of a "first phase," in the form of an 85:15 PLGA polymer-rich matrix, that is not miscible with a "second phase," in the form of discrete, everolimus-rich domains that are dispersed throughout the 85:15 PLGA polymer-rich matrix; (c) everolimus is a "therapeutic agent," "immunomodulator," and "compound inhibiting angiogenesis" in that it has immunosuppressant properties, has anti-angiogenic properties, and is included in a locally therapeutic amount; and (d) everolimus is released at varying rates over time from such ultrathin bioabsorbable polymer.

84. At one or more times during the period November 20, 2011 to August 18, 2020, BSX directly infringed '296 patent claims 1, 11, 12, 17, and 26 by selling and offering for sale, and by importing, SYNERGY BP Stents, in and into the United States, in violation of 35 U.S.C. § 271(a). Further, at one or more times during the period November 20, 2011 to August 18, 2020, BSX infringed'296 patent claims 1, 11, 12, 17, and 26 by making, importing, and using SYNERGY BP Stents in the United States in violation of 35 U.S.C. § 271(a).

85. BSX's direct infringement of '296 patent claims 1, 11, 12, 17, and 26 was willful during the November 20, 2011 to August 18, 2020 time frame. BSX knew of the '296 patent and TissueGen's development plans as early as 2011, including through prosecution of U.S. Patent Application No. 11/395964, Mr. Bluni, Ms. Moynihan, and Mr. Ballinger. BSX was again made

aware of the '296 patent no later than in or about January of 2018 after Plaintiffs filed this suit on November 20, 2017. Further, on information and belief, either (a) Ms. Moynihan, Mr. Ballinger, and/or others at BSX reviewed the '296 patent and determined that the SYNERGY BP Stents potentially infringed one or more '296 patent claims, or (b) such persons purposefully took actions—such as choosing not to initiate an *inter partes* review challenge, choosing not to file a counterclaim for noninfringement, and choosing not to file a counterclaim for invalidity—to prevent BSX from learning of the risk that its SYNERGY BP Stents potentially infringed one or more '296 patent claims. Thereafter, BSX continued to directly infringe '296 patent claims 1, 11, 12, 17, and 26 as set forth in the proceeding paragraph.

86. BSX's direct infringement has caused damage to Plaintiffs, and Plaintiffs are entitled to recover from BSX the damages they sustained as a result of BSX's wrongful acts in an amount comparable to the amount BSX paid for rights to Guidant's everolimus eluting stent technology shared with Abbott. Further, in view of BSX's knowing and/or willfully blind direct infringement that continued during this lawsuit, Plaintiffs should be awarded at least an additional 100% of the damages they have sustained pursuant to 35 U.S.C. § 284.

COUNT II: INDIRECT INFRINGEMENT

87. Plaintiffs repeat and re-allege each and every allegation of the prior paragraphs as though set forth fully herein.

88. At one or more times during the period November 20, 2011 to August 18, 2020, one or more of BSX's divisions, subsidiaries, affiliates, or another other party with contractual obligations to BSX directly infringed '296 patent claims 1, 11, 12, 17, and 26 by selling, offering for sale, and/or importing SYNERGY BP Stents, in or into the United States, in violation of 35 U.S.C. § 271(a). Further, at one or more times during the period November 20, 2011 to August 18, 2020, one or more clinicians, surgeons, or other third parties directly infringed '296 patent claims

1, 11, 12, 17, and 26 by using SYNERGY BP Stents in the United States in violation of 35 U.S.C. § 271(a).

89. In violation of 35 U.S.C. § 271(b), BSX actively induced third-party direct infringement of '296 patent claims 1, 11, 12, 17, and 26 by directing, contracting with, supporting, and/or otherwise encouraging the use, sale, offer for sale, and/or importation of SYNERGY BP Stents, in the United States, during the November 20, 2011 to August 18, 2020 time frame. During that same period, BSX encouraged use of SYNERGY BP Stents by surgeons and other clinicians, in the United States, including by sponsoring clinical trials requiring use of SYNERGY BP Stents, providing instructions for using SYNERGY BP Stents, and providing education and customer support services to surgeons, clinicians, and other users of SYNERGY BP Stents. In addition, on information and belief, during the same period, BSX actively encouraged one or more of its divisions, subsidiaries, and affiliates to sell, offer to sell, and/or import SYNERGY BP Stents, in and into the United States. On information and belief, BSX's actions to encourage infringement included, among other things, contracting with such third parties concerning the purchase of SYNERGY BP Stents and supplying components of SYNERGY BP Stents to such third parties to facilitate their manufacture and subsequent sale, offers for sale, and importations of SYNERGY BP Stents, in and into the United States.

90. BSX knew of the '296 patent and TissueGen's development plans as early as 2011, including through prosecution of U.S. Patent Application No. 11/395964, Mr. Bluni, Ms. Moynihan, and Mr. Ballinger. BSX was again made aware of the '296 patent no later than in or about January of 2018 after Plaintiffs filed this suit on November 20, 2017. Further, on information and belief, either (a) Ms. Moynihan, Mr. Ballinger, and/or others at BSX reviewed the '296 patent and determined that the SYNERGY BP Stents potentially infringed one or more

'296 patent claims, or (b) such persons purposefully took actions—such as choosing not to initiate an inter partes review challenge, choosing not to file a counterclaim for noninfringement, and choosing not to file a counterclaim for invalidity—to prevent BSX from learning of the risk that its SYNERGY BP Stents potentially infringed one or more '296 patent claims. Thereafter, BSX continued to direct, contract with, support, and/or otherwise encourage third parties to take actions that directly infringed '296 patent claims 1, 11, 12, 17, and 26 as set forth in the proceeding paragraph.

91. BSX's induced infringement has caused damage to Plaintiffs, and Plaintiffs are entitled to recover from BSX the damages they sustained as a result of BSX's wrongful acts in an amount comparable to the amount BSX paid for rights to Guidant's everolimus eluting stent technology shared with Abbott. Further, in view of BSX's knowing and/or willfully blind direct infringement that continued during this lawsuit, Plaintiffs should be awarded at least an additional 100% of the damages they have sustained pursuant to 35 U.S.C. § 284.

COUNT III: ENHANCED DAMAGES

92. BSX knew of the '296 patent and TissueGen's development plans as early as 2011, including through prosecution of U.S. Patent Application No. 11/395964, Mr. Bluni, Ms. Moynihan, and Mr. Ballinger. BSX was again made aware of the '296 patent no later than in or about January of 2018 after Plaintiffs filed this suit on November 20, 2017. Further, on information and belief, either (a) Ms. Moynihan, Mr. Ballinger, and/or others at BSX reviewed the '296 patent and determined that the SYNERGY BP Stents potentially infringed one or more '296 patent claims, or (b) such persons purposefully took actions—such as choosing not to initiate an inter partes review challenge, choosing not to file a counterclaim for noninfringement, and choosing not to file a counterclaim for invalidity—to prevent BSX from learning of the risk that its SYNERGY BP Stents potentially infringed one or more '296 patent claims. Thereafter, BSX

continued to directly infringe '296 patent claims 1, 11, 12, 17, and 26 as set forth in Count I herein and further continued to direct, contract with, support, and/or otherwise encourage third parties to take actions that directly infringed '296 patent claims 1, 11, 12, 17, and 26 as set forth in Count II herein.

93. BSX's direct infringement of '296 patent claims 1, 11, 12, 17, and 26 was willful during the November 20, 2011 to August 18, 2020 time frame; and (b) BSX actively induced such third party direct infringement of '296 patent claims 1, 11, 12, 17, and 26 by directing, contracting with, supporting, and/or otherwise encouraging the use, sale, offer for sale, and/or importation for sale, in the United States, of SYNERGY BP Stents during the November 20, 2011 to August 18, 2020 time frame.

94. BSX's induced and willful infringement has caused damage to Plaintiffs, and Plaintiffs are entitled to recover from BSX the damages they sustained as a result of BSX's wrongful acts in an amount comparable to the amount BSX paid for rights to Guidant's everolimus eluting stent technology shared with Abbott. Further, in view of BSX's knowing and/or willfully blind direct infringement that continued during this lawsuit, Plaintiffs should be awarded at least an additional 100% of the damages they have sustained pursuant to 35 U.S.C. § 284**.**

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray for entry of judgment against Defendant BSX as follows:

A. Declaring that BSX has directly infringed the asserted patent, and did so willfully;

B. Declaring that BSX has actively induced direct infringement of the asserted patent;

C. Awarding to Plaintiffs a reasonable royalty, for BSX's infringement of the asserted patent during the November 20, 2011 to August 18, 2020 time frame, in an amount

comparable to the amount BSX paid for rights to Guidant's everolimus eluting stent technology shared with Abbott;

D. Awarding to Plaintiffs enhanced damages of no less than an additional 100% of the reasonable royalty award pursuant to 35 U.S.C. § 284 in view of BSX's knowing and/or willfully blind direct and induced infringement;

E. Awarding to Plaintiffs prejudgment interest in an amount according to proof;

F. Awarding to Plaintiffs attorneys' fees as permitted by law; and

G. Awarding such other costs and further relief as the Court may deem just and proper.

Respectfully Submitted,

/s/ Stamatios Stamoulis

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CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2021, the foregoing was served via electronic transmission (CM/ECF) upon all counsel of record for the parties.

/s/ Stamatios Stamoulis
Stamatios Stamoulis