UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SPINAL GENERATIONS, LLC Plaintiff, v. DEPUY SYNTHES, INC., SYNTHES USA, LLC, and SYNTHES USA PRODUCTS, LLC, Defendants.	Civil Action No. **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Spinal Generations, LLC ("Plaintiff" or "SG") hereby brings this complaint for patent infringement against Defendants DePuy Synthes, Inc. ("DePuy Synthes"), Synthes USA, LLC ("Synthes USA"), and Synthes USA Products, LLC ("Synthes Products USA") (collectively, "Defendants" or "DePuy"). For its complaint, SG alleges as follows:

INTRODUCTION

1. In 2002, Dr. Patrick Sweeney, an orthopedic surgeon, invented a revolutionary surgical screw used to repair fractured bones. Unlike prior surgical screws, Dr. Sweeney's novel design contains a hollow cavity disposed inside the screw shaft with pre-designed openings at points along the shaft. It also includes a "cannulated, fenestrated insert" with a hollow cavity and openings that goes inside the screw. Together, the screw and insert allow a surgeon to deliver a precise amount of medicine, including binding agents and other fillers such as cement, into exact locations around the fracture, to maximize the effectiveness of the repair to the injured bone.

2. Dr. Sweeney applied for and has received nine U.S. Letters Patent for his invention. His invention also has been patented throughout Europe. Dr. Sweeney assigned his patents to SG, which licensed the patents to another Sweeney-owned company, Flow-FX, to make and sell his patented screw and insert—called the "Flow-Nail" and "Flow-Screw."

3. In 2014-2015, Dr. Sweeney met with DePuy Synthes, a wholly-owned subsidiary of Johnson & Johnson, to discuss a potential partnership for the manufacture, marketing, and distribution of the patented invention. During the meeting between Dr. Sweeney and multiple high-level DePuy Synthes executives, Dr. Sweeney showed DePuy Synthes his Flow-Nail design and explained the advantages of the patented Flow-Nail, including how the design enabled the delivery of injectable bone void fillers through side openings. Dr. Sweeney repeatedly stressed that his product was protected by issued patents. While DePuy Synthes declined to partner with Dr. Sweeney, they also gave no indication that they intended to introduce an infringing, competing product in the United States. But that's exactly what they did: After waiting two years, DePuy Synthes introduced its TFNA product—which is virtually indistinguishable from the Flow Nail product that Dr. Sweeney had presented to them—in the United States, even using some of the same terminology as the Flow-Nail. And DePuy Synthes's TFNA product directly reads on claims in five SG patents. Accordingly, SG brings this action for patent infringement, seeking compensation for DePuy Synthes's unauthorized use of Dr. Sweeney's patented invention.

NATURE OF THE ACTION

4. This is a patent infringement action. Plaintiff SG asserts that Defendants have directly and indirectly infringed one or more claims of five of its United States Patents (collectively, the "Patents-in-Suit"), which were duly issued by the United States Patent and Trademark Office ("USPTO"), copies of which are attached as Exhibits 1-5 hereto:

Exh.	U.S. Patent No.	Title
1	7,527,611 (the "'611 patent")	Method and Device for Delivering Medicine to Bone
2	7,575,572 (the "'572 patent")	Method and Device for Delivering Medicine to Bone
3	8,062,270 (the "'270 patent")	Method and Device for Delivering Medicine to Bone

Exh.	U.S. Patent No.	Title
4	8,808,337 (the "'337 patent")	Method and Device for Delivering Medicine to Bone
5	9,949,777 (the "'777 patent")	Method and Device for Delivering Medicine to Bone

5. Plaintiff seeks monetary damages sufficient to compensate it for Defendants' infringement of the Patents-in-Suit, as well as a declaration that this is an exceptional case, a permanent injunction, enhanced damages, attorneys' fees and costs, and interest on the judgment.

PARTIES

6. Plaintiff SG is a limited liability company organized under the laws of the state of Illinois, having a principal place of business at 9301 West 191st Street, Mokena, IL 60448.

7. Defendant DePuy Synthes is a corporation organized under the laws of the state of Delaware. Based on publicly-available information, DePuy Synthes has a principal place of business at 325 Paramount Drive, Raynham, MA.

8. Defendant Synthes USA is a limited liability company organized under the laws of the state of Delaware. Based on publicly-available information, Synthes USA has a principal place of business at 1101 Synthes Avenue, Monument, CO 80132.

9. Defendant Synthes Products USA is a limited liability company organized under the laws of the state of Delaware. Based on publicly-available-information, Synthes Products USA has a principal place of business at 1302 Wrights Lane East, West Chester, PA 19380.

JURISDICTION AND VENUE

10. Plaintiff repeats and re-alleges each of the allegations set forth in Paragraphs 1-9 *supra* as if fully set forth herein.

11. This Court has subject matter jurisdiction over this case under 28 U.S.C. §§ 1331 and 1338(a), because the claims asserted by Plaintiff against Defendants arise under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*.

12. This Court has personal jurisdiction over each Defendant at least because each Defendant resides in the state of Delaware. Each Defendant resides in the state of Delaware at least because each Defendant is organized under the laws of the state of Delaware.

13. Venue is proper in this Court as to each Defendant under 28 U.S.C. § 1400(b) at least because each Defendant resides in this judicial district. Each Defendant resides in this judicial district at least because each Defendant is organized under the laws of the state of Delaware.

SPINAL GENERATIONS AND DR. PATRICK SWEENEY

14. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-13 *supra* as if fully set forth herein.

15. The sole inventor of the Patents-in-Suit is Dr. Patrick Sweeney, an orthopedic surgeon based out of Mokena, Illinois. Dr. Sweeney graduated from Northwestern University Medical School in 1988. He completed a Residency in Orthopedic Surgery at the McGaw Medical Center of Northwestern University in 1993, and completed a Fellowship in Orthopedic Surgery of the Spine at the University of Louisville in 1994. Dr. Sweeney is board-certified as an Orthopaedic Surgeon by the American Board of Orthopaedic Surgery.

16. Dr. Sweeney specializes in minimally invasive orthopedic surgery. He operated his own medical practice, Minimally Invasive Spine Specialists, which was based in Mokena, Illinois, and is now retired from active practice.

17. SG is the owner, by assignment, of all right, title, and interest in and to each of the Patents-in-Suit, including all rights to sue for past damages. The assignment documents, assigning all rights from Dr. Sweeney to SG, are recorded at the United States Patent and Trademark Office. Copies of the assignments are attached as Exhibit 6 hereto.

THE PATENTS-IN-SUIT

18. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-17 *supra* as if fully set forth herein.

19. The Patents-in-Suit describe and claim an innovative surgical system that Dr. Sweeney developed in the course of his medical practice. The patented system allows surgeons to deliver precise quantities of a desired substance, such as medication or bone cement, to a precise location at, on, or within a patient's bone. The patented system has improved patient outcomes in a variety of surgical situations, including femoral fracture repair in osteoporotic patients.

20. The earliest-filed application for the Patents-in-Suit is U.S. Application No. 10/620,287 (the "'287 Application"), filed on July 15, 2003, which issued as the '572 patent on August 18, 2009. Ex. 2 at 1. All of the other Patents-in-Suit claim priority to the '287 Application, either as continuations or as continuations-in-part. Accordingly, the general disclosures of the Patents-in-Suit can be summarized by reference to the disclosures of the '572 patent.

21. As the '572 patent explains, at the time of the invention, "[d]elivery of medicants or therapeutics to bones [was] an often desirable but difficult-to-achieve process, especially if one desire[d] to focus the delivery to the interior of a bone or to a particular area in a bone." Ex. 2, 1:15-18. Various systems to deliver medicants or therapeutics to bone were known in the prior art. *Id.*, 1:15-51. However, all of them had significant drawbacks.

22. For instance, "[d]elivery pins or needles, such as those disclosed in U.S. Pat. No. 6,210,376 … [were] sometimes used to deliver medication or other fluids into bone." *Id.*, 1:18-28. However, such pins or needles were not able to "deliver … medicants or fluids to a specific area of interest within a bone." *Id.* They also could "not serve as fixation screws for holding two or more bones or bone pieces in a fixed spatial relationship with respect to each other." *Id.*

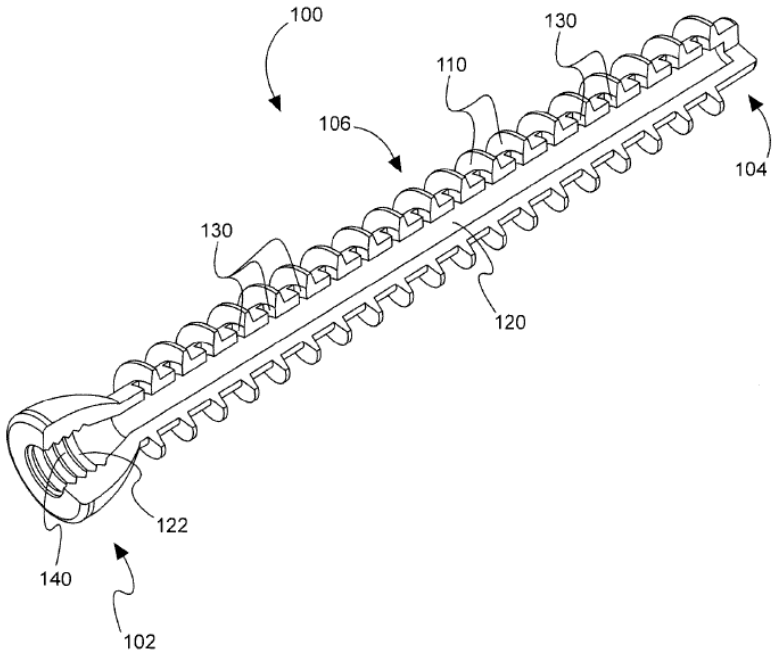
23. It was also known to use "[b]one screws … to deliver liquids such as bone cements to the interior of a bone, [as] disclosed in U.S. Pat. Nos. 5,047,030 and 6,214,012." *Id.*, 1:29-45. However, prior art bone screws "provide[d] no way to control or regulate the amount of substance delivered," and did not allow "[s]ubstance delivery [to] be directed to certain areas within the bone and not others without changing the location or configuration of the bone screw." *Id.*

24. Thus, Dr. Sweeney realized, "a need exist[ed] for a device capable of delivering a substance to a bone, especially to specific areas within the bone, such as a fracture interface." *Id.*, 1:46-51. He realized that "a further need exist[ed] for the ability to customize the delivery location and amount during the course of an operation, once the bone screw is in place." *Id.*

25. Dr. Sweeney's invention filled these needs, creating—for the first time—a surgical system that could deliver the exact amount of desired therapeutic substance to the exact desired location at, on, or within a patient's bone, without repositioning the bone screw.

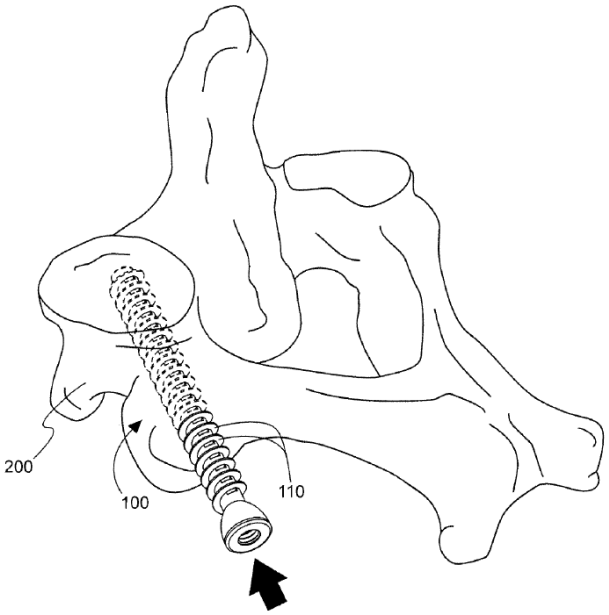
26. Dr. Sweeney's invention includes two major components: (i) a cannulated, fenestrated bone screw; and (ii) a cannulated, fenestrated insert. Ex. 2, 1:55-2:38. In the Patents-in-Suit, "cannulated" means "that the screw or insert comprises a hollow cavity disposed inside at least part of its shaft." *Id.*, 3:25-27. "Fenestration," as used in the patented invention, "broadly [ ] include[s] any slot, gap, or perforation that defines an opening between the inside of the cannulated portion of the screw or insert to the outside of the screw or insert whereby a desired substance may be delivered." *Id.*, 3:45-50. Thus, a "cannulated, fenestrated bone screw" is a bone screw with a hollow cavity disposed inside at least a part of its shaft, having slots, gaps, or perforations that define openings between the cavity and the outside of the screw. *Id.* A "cannulated, fenestrated insert" is an insert with a hollow cavity disposed inside at least a part of its shaft, having slots, gaps, or perforations that define openings between the cavity and the outside of the insert. *Id.*

27. One embodiment of a cannulated, fenestrated bone screw according to the invention is shown in Figure 1 of the '572 patent, reproduced below:



28. As seen above, the bone screw 100 has two ends 102, 104 connected by a shaft 106. *Id.*, 4:28-42. The interior of the shaft 106 includes a cannulated portion (cavity) 120. *Id.* The exterior of the shaft 106 includes threads 110 which assist in affixing the bone screw to the patient's bone. *Id.* A plurality of fenestrations 130 are disposed along the length of the shaft 106. *Id*. The fenestrations provide openings through which material can flow from the cannulated portion 120 to the exterior of the bone screw 100. *Id.*

29. Figure 2 of the '572 patent depicts the bone screw 100 after it has been implanted into a patient's bone, which—in the exemplary figure—is a hip bone:



30. Figures 3a and 3b of the '572 patent, reproduced below, show an embodiment of the cannulated, fenestrated insert with a single fenestration:

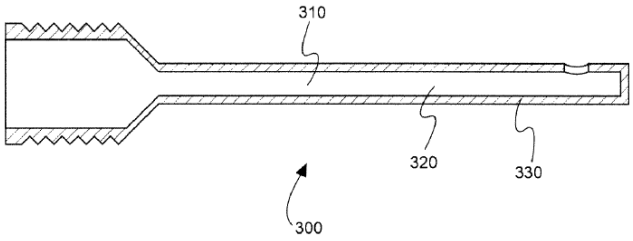


Fig. 3a

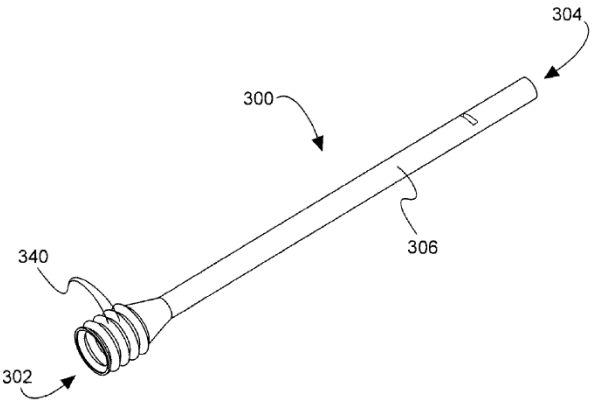


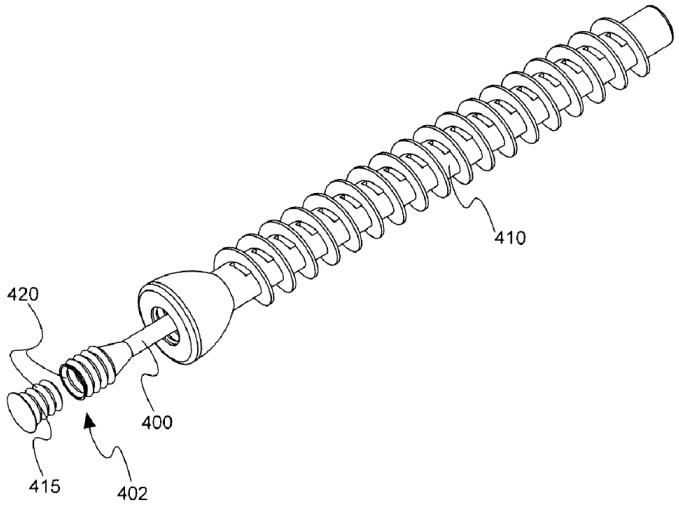
Fig. 3b

31. Figure 3a is a schematic cross sectional view of the insert, while Figure 3b is a perspective view. The insert 300 includes ends 302 and 304 connected by a shaft 306. *Id.*, 5:7-34. The shaft 306 has a cannulated portion 310 comprising a hollow cavity 320 and an insert wall 330. *Id.* In this embodiment, a single fenestration is disposed along the insert wall 330 to provide a path

for material to flow from the hollow cavity 320 to the exterior of the insert 300. *Id.*

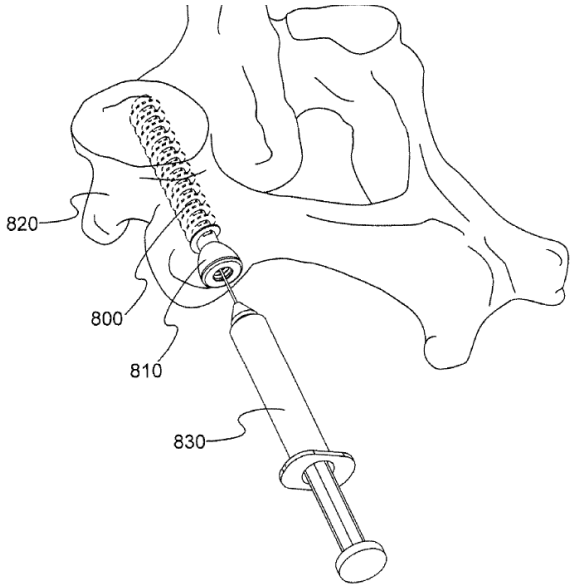
32. While Figures 3a and 3b show an insert with only one fenestration, and show that the fenestration is approximately rectangular in shape, the '572 patent explains that any "appropriate number, size, shape, and location of insert fenestrations can be chosen by the practitioner without undue experimentation to provide a delivery pathway between at least one end of the insert and the one or more bone-screw fenestrations." *Id.*, 5:62-6:13.

33. Figure 4 of the '572 patent, reproduced below, shows the insert 400 after it has been inserted into the bone screw 410:



34. In this embodiment, the insert 400 has a "tight but sliding fit" within the bone screw. *Id.*, 5:33-61. This "tight but sliding fit" allows the insert to be "rotated with respect to the screw to achieve alignment of certain of the insert and bone screw fenestrations." *Id.* That is, by rotating the insert within the bone screw, the surgeon can align the insert fenestration(s) with the exact bone screw fenestration(s) to which he wishes to deliver the substance. *Id.* This enables the surgeon to deliver the substance to the exact desired location at or within the patient's bone.

35. Figure 8a of the '572 patent, reproduced below, shows an embodiment in which a syringe is used to deliver material to the insert for delivery to the patient's bone:



36. As seen above, the syringe 830 is used to inject the substance into the hollow cavity of the insert 810. *Id.*, 8:1-28. Upon injection, the material flows through the hollow cavity of the insert 810, through any fenestration(s) of the insert 810 that are aligned with the fenestration(s) of the bone screw 800, to the desired location at bone 820. *Id.*

37. Dr. Sweeney's inventive system provided multiple advantages over the prior art. First, it permitted surgeons to deliver therapeutic substances to the exact desired location at the patient's bone, without requiring repositioning of the bone screw. Second, by blocking all bone screw fenestrations other than the ones at the desired location, the insert prevents the substance from leaking into undesired locations, which could harm the patient. Third, by blocking all bone screw fenestrations other than the ones at the desired location, the insert prevents bone fragments, fat, blood, or other obstructions from entering the bone screw. Fourth, by ensuring that the substance to be delivered is released only at the desired location, the invention prevents waste.

38. The Patents-in-Suit explain that the "substance" that can be delivered via the insert and bone screw can be any "compound[] that [is] useful when delivered to the vicinity of a bone," such as "[s]ubstances … to help treat … fractured or otherwise injured bones." *Id.*, 7:53-60. These

include "bone cements." *Id.*, 1:29-45.

DEFENDANTS AND THE ACCUSED INSTRUMENTALITIES

39. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-38 *supra* as if fully set forth herein.

40. DePuy is "the orthopaedics company of Johnson and Johnson." Ex. 7 ("TFN-ADVANCED® Proximal Femoral Nailing System (TFNA) Surgical Technique") at 1. Johnson and Johnson ("J&J") is "the world's largest and most broadly based healthcare company." Ex. 8 (https://www.jnj.com/about-jnj, accessed 10/14/2022) at 1.

41. Prior to becoming part of J&J, DePuy, Inc., was an independent orthopedic device manufacturer based out of Warsaw, Indiana. *See* Ex. 9 (https://www.meddeviceonline.com/doc/johnson-johnson-buys-depuy-for-35-billion-0001, "Johnson & Johnson Buys DePuy for $3.5 Billion") at 1. In 1998, J&J acquired DePuy, Inc., at which point it became a J&J subsidiary: "DePuy, a Johnson & Johnson Company." *Id.*

42. Prior to becoming part of J&J, Synthes, Inc. was an independent "premier global manufacturer of orthopaedic devices." Ex. 10 (https://www.jnj.com/media-center/press-releases/johnson-johnson-and-synthes-announce-definitive-merger-agreement-to-create-worlds-most-innovative-and-comprehensive-orthopaedics-business, "Johnson & Johnson and Synthes Announce Definitive Merger Agreement to Create World's Most Innovative and Comprehensive Orthopaedics Business") at 1. In 2012, J&J acquired Synthes. Ex. 11 (https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-completion-of-synthes-acquisition, "Johnson & Johnson Announces Completion of Synthes Acquisition") at 1. Synthes was then "integrated with the DePuy franchise to establish the DePuy Synthes Companies of Johnson & Johnson … the world's most … comprehensive orthopaedics business." *Id.*

43. As part of J&J, DePuy sells a surgical system called the "TFN-Advanced Proximal

Femoral Nailing System (TFNA)" ("TFNA"). The TFNA system is "intended for treatment of [femur/hip] fractures in adults and adolescents (12-21) in which the growth plates have fused." Ex. 7 at 5. The types of femur/hip fractures that can be treated with the TFNA system include "[s]table and unstable pertrochanteric fractures," "[i]ntertrochanteric fractures," "[b]asal neck fractures," "[c]ombinations of pertrochanteric, intertrochanteric, and basal neck fractures," "[s]ubtrochanteric fractures," and "[p]roximal or distal nonunions, malunion and revisions." *Id.*

44. DePuy sells two versions of the TFNA system: the "long nail" version (below at left), and the "short nail" version (below at right) (*id.*):

45. "Both the short and long [nail] TFNA Systems are … indicated for use with cleared, polymethylmethacrylate (PMMA) bone cement that can be delivered through the fenestrated blade or screw via a cannula in skeletally mature adults with risk of cut-out or device instability due to poor bone quality." *Id.* The PMMA bone cement "provides increased stability" in the interface between the TFNA system and the bone, which is "especially [important] in patients with osteoporotic bone." Ex. 12 ("TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA) Comparative Evaluation of Head Element Fixation") at 1. DePuy calls its PMMA bone cement "TRAUMACEM V+" ("TRAUMACEM"), and calls its system for delivery of TRAUMACEM

the "TRAUMACEM V+ Augmentation System" ("Augmentation System"). Ex. 7 at 7.

46. The TFNA System comprises a number of components. These include:

a. The "nail:" As shown in Paragraph 44 above, the TFNA system includes a "nail," which is a metallic structure inserted along the axis of the femur. *See* Ex. 7 at 69-73 (describing various nails available with the TFNA system). The nail can be either "long" or "short." *Id.* The nail serves as an anchor into which the "head" will be inserted.

b. The "head:" The TFNA system includes a "head" which is inserted into the nail to stabilize and repair the fracture. *Id.* at 74. Two types of heads are available: "TFNA Screws" (below at top), and "TFNA Helical Blades" (below at bottom) (*id.*):

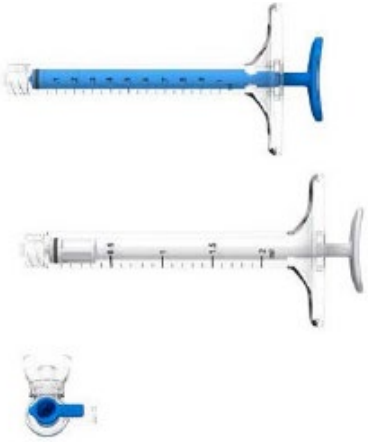
Both types of heads are "cannulated," i.e., they each contain a hollow internal chamber that allows a substance to flow. *Id.* Both types of heads are also "fenestrated" (*id.* at 5): i.e., they each have a series of holes that allow the substance to flow from the cannula to the head exterior.

c. The "Augmentation System:" The Augmentation System, which is used to deliver bone cement to bone, has a number of components, including:

i. Bone Cement kit: The Augmentation System includes a Bone Cement kit, which contains the actual bone cement, and the components needed to mix and prepare the bone cement (*id.* at 79):

07.702.040S	TRAUMACEM V+ Injectable Bone Cement, sterile Containing: 1× TRAUMACEM V+ mixer with sterilization lid 1× Monomer glass ampoule 1× Cement mixing and transferring lid	

ii. Syringe Kit: The Augmentation System includes a Syringe Kit, which contains syringes used to inject the bone cement into the system (*id.*):

03.702.150S	TRAUMACEM V+ Syringe Kit, 4 x 1 mL, 2 x 2 mL, sterile Containing: 4 × Blue 1 mL syringes 2 × White 2 mL syringes 1× One-way stopcock	

iii. Side-Opening Cannula: The Augmentation System also includes a Side-Opening Cannula, which is used to direct the bone cement to the specific desired locations at the patient's bone (*id.*):

03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile Containing: 1× Side-opening cannula, with Luer-lock 1× Plunger	

47. Exhibit 7, a DePuy "Surgical Technique" Guide, provides detailed, step-by-step instructions on how to insert the TFNA system into a patient, and how to use the Augmentation

System to apply bone cement. These steps include:

a. Inserting the nail: After making appropriate preparations, DePuy instructs surgeons to insert the nail along the length of the femur (*id.* at 19):

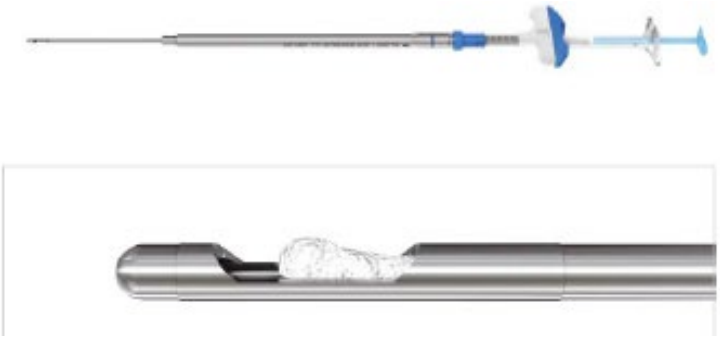
b. Inserting the head: After making further preparations, DePuy instructs surgeons to insert the head through the nail and into the femur head (*id.* at 35):

c. Adjusting the side-opening cannula: DePuy then instructs surgeons to adjust the length of the side-opening cannula to align the opening in the cannula with the desired fenestrations in the head. *Id.* at 40. "Length adjustments are made by turning the

sleeve (2), while holding the handle of the side-opening cannula (1). One clockwise turn of the sleeve relates to 5 mm lateral axial movement of the side-opening cannula." *Id.*:

d. Preparing the cement and filling the injection syringes: DePuy then instructs surgeons to prepare the cement, and fill syringes with the cement. *Id.* at 43-44.

e. Prefilling the side-opening cannula: DePuy then instructs surgeons to prefill the side-opening cannula with cement via the syringes, "until the cement is coming out of the side opening," as shown below (*id.* at 46):



f. Inserting the side-opening cannula: DePuy then instructs surgeons to insert the side-opening cannula into the head, "[c]onfirm[ing] that the selected length on the side-opening cannula corresponds with the length of the [head]" (*id.* at 47):

g. Injecting the cement: Finally, DePuy instructs surgeons to inject the cement "using 1 mL syringes." *Id.* at 48. DePuy explains that the surgeon can "[o]ptimize the filling by rotating the handle to inject cement around the blade/screw." *Id.* To assist in this, there is an "arrow on the handle [that] indicates the [rotational] position of the side-opening window of the cannula." *Id.* DePuy further instructs that, "[i]f noted under fluoroscopy that the cement is traveling towards the joint surface," the surgeon should "move the cannula laterally by rotating the sleeve 1 clockwise turn." *Id.* Thus, DePuy expressly instructs surgeons to adjust the lateral and rotational position of the opening in the side-opening cannula to optimize the delivery of cement to desired locations. *Id.*

48. The TFNA system, with the Augmentation System, was first sold in the United States in October 2017. Ex. 13 (https://www.jnj.com/media-center/press-releases/new-system-designed-to-enhance-implant-fixation-for-hip-fracture-patients-with-poor-bone-quality-launches-in-the-us, "New System Designed to Enhance Implant Fixation for Hip Fracture Patients with Poor Bone Quality Launches in the U.S.") at 1.

49. On information and belief, DePuy has continually sold the TFNA system, with the Augmentation System, in the United States since it was introduced in October 2017.

DEFENDANTS' PRE-SUIT AWARENESS OF THE PATENTS-IN-SUIT

50. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-49 *supra* as if fully set forth herein.

51. Defendants were aware of Dr. Sweeney, his invention, and the Patents-in-Suit years before they introduced the TFNA Augmentation system in the United States. Indeed, Dr. Sweeney is the one who introduced Defendants to his invention, through a series of communications aimed at establishing a collaboration between Defendants and his company, Flow-FX. Yet, rather than collaborate, Defendants went behind his back, stole his idea, and used it to make TFNA—a product that has been so successful, it has become the centerpiece of DePuy's Trauma product line, and has nearly pushed Dr. Sweeney's competing product off of the market.

52. In March 2010, Dr. Sweeney formed Orthopedic Generations LLC d/b/a Flow-FX ("Flow-FX") as an Illinois Limited Liability Corporation. Flow-FX was created to develop, manufacture, and market orthopedic surgical devices based on Dr. Sweeney's inventions, including the Patents-in-Suit. In September 2011, the Illinois Flow-FX LLC was dissolved. In October 2011, Orthopedic Generations LLC (again doing business as Flow-FX) was re-formed as a Delaware Limited Liability Corporation. The Delaware Flow-FX LLC remains active and in good standing. Dr. Sweeney is the sole owner (i.e., Member) of Flow-FX.

53. Under license from SG, Flow-FX makes and sells a product that practices the Patents-in-Suit: "Flow-Nail." Ex. 14 (Flow-Nail Surgical Technique) at 1. Flow-FX's documentation for Flow-Nail touts the advantages of its "[p]atented side-port cannula," which "delivers bone void filler through fenestrations while protecting the hip joint from unintended intrusion of biologic material." *Id.* at 4; *see also* Ex. 15 (Flow-Nail Information Sheet) at 1 (same).

54. On March 10, 2014, Flow-FX filed a Section 510(k) Premarket Notification for

Flow-Nail with the Food and Drug Administration (FDA). The FDA approved the Premarket Notification on July 2, 2014. Ex. 16 (K140601 Premarket Notification Summary) at 3. Thus, as of July 2, 2014, Flow-FX has been authorized to market Flow-Nail in the United States.

55. In July 2014, while Flow-FX had the ability to make and sell limited numbers of Flow-Nail products, Dr. Sweeney wished to market the product on a nationwide, industry-wide scale. Accordingly, throughout 2014-2015, Dr. Sweeney reached out to J&J and DePuy—the "world's most … comprehensive orthopaedics business" (Ex. 10 at 1)—to see if they would partner with Flow-FX to manufacture, market, and distribute Flow-Nail.

56. On January 8, 2014, Dr. Sweeney emailed Matthew Page, a Midwest Region Sales Consultant for DePuy. *See* Ex. 17 (Matthew Page LinkedIn) at 1. In the email, Dr. Sweeney told Mr. Page that he would "like to speak with someone [at DePuy] re- domestic and international distribution of our 3 product lines," including "Flow-Nail." Ex. 18 (1/8/2014 email, P. Sweeney to M. Page) at 1. Dr. Sweeney advised Mr. Page that Flow-FX "expect[ed] to have 510k clearance" on Flow-Nail "in the next 5 months." *Id.* As attachments to the email, Dr. Sweeney provided copies of two of the Patents-in-Suit: the '611 and '572 patents. *Id.* He also attached a "Docket Report" generated on December 10, 2012 by his patent prosecution firm, Foley & Lardner. *Id.*; *see also* Ex. 19 (Docket Report). The Docket Report listed the '611 and '572 patents as patents that had been "granted" to Dr. Sweeney. *Id.* It also noted that the '270 patent had been "granted," and listed App. No. 12/427,520, which later issued as the '337 patent, as "pending."

57. On April 13, 2015, Dr. Sweeney spoke with Dr. Hassan Serhan, a Distinguished Engineering Fellow at DePuy. *See* Ex. 20 (Hassan Serhan LinkedIn) at 3. At the time, Dr. Serhan "[l]ed the Front-End and external innovation program as well as evaluations of all external new ideas to feed [the] DePuy Synthes Spine pipeline," and "negotiat[ed] and structure[ed] external

collaborative R&D agreements for DePuy." *Id.* Thus, Dr. Serhan was a senior DePuy employee, with authority to enter into "external collaborat[ions]" of the type Dr. Sweeney was proposing. *Id.*

58. After Dr. Sweeney spoke with Dr. Serhan, he sent him an email on April 13, 2015. *See* Ex. 21 (4/13/2015 email, P. Sweeney to H. Serhan). The email attached a PowerPoint presentation titled "Flow-FX J&J DePuy Synthes 4-13-2015." *Id.*; *see also* Ex. 22 (4/13/2015 PowerPoint Presentation). Dr. Sweeney asked Dr. Serhan to review the presentation, noting that his invention was a "12 y[ea]r project," and that "implants capable of delivering biologics in a precise manner will shortly become essential to meet the demands of the patient population." Ex. 21 at 1. He further invited Dr. Serhan to review Flow-FX's "web site." *Id.*

59. On the morning of April 17, 2015, Dr. Sweeney delivered his presentation to a number of senior DePuy executives and engineers. These included: (i) Dr. Serhan; (ii) Dr. Doug Buechter, DePuy's Worldwide Director of New Technologies (Ex. 23 (Doug Buechter LinkedIn) at 1); (iii) Nick Pachuda, Worldwide Vice President of External innovation and Enabling Technologies for J&J's Medical Device Group (Ex. 24 (Nick Pachuda LinkedIn) at 1); and (iv) Martin Reynolds, Director of New Business Development for J&J (Ex. 25 (Martin Reynolds LinkedIn) at 1). *See* Ex. 26 (4/17/2015 email, P. Sweeney to H. Serhan *et al*.) at 1.

60. The presentation introduced DePuy and J&J to the Flow-FX product portfolio, including the "Flow-Nail" product, which provides "[p]recision delivery of BVF [bone void filler] to intertrochanteric/subtrochanteric fractures." Ex. 22 at 3. The presentation included a rendering of the Flow-Nail product implanted in a patient's femur, which is almost indistinguishable from the DePuy TFNA rendering shown in Paragraph 47(f) *supra* (Ex. 22 at 3):

61. The presentation provided details about the structure of the Flow-Nail product, including its "Side Port Cannula" which "[e]nables the delivery of injectable bone void fillers … to the trochanteric / femoral neck and head regions." *Id.* at 11. The presentation touted the "***Unique*** Instrumentation" provided by the "Side Port Cannula," whose "[d]esign enhances [the] ability to accurately target the application to the effected [sic] area." *Id.* at 14. The presentation noted the extensive testing and verification, including cadaver testing, that Dr. Sweeney had performed to confirm the safety and efficacy of the Flow-Nail system. *Id.* at 16-17.

62. The presentation proposed a timeline in which the Flow-Nail product would be launched in the United States by "Q2, 2015." *Id.* at 18. It concluded by proposing that J&J should "Partner with Flow-FX," because the partnership would "Change the World" and "affect the lives of MILLIONS of people," with "Estimated Sales" of over "$15B over ***IP life***." *Id.* at 19. During the presentation, Dr. Sweeney explained that the "IP [intellectual property] life" referenced in the

slide included the Patents-in-Suit, which cover Flow-Nail.

63. After the presentation, Dr. Sweeney emailed the J&J/DePuy participants, thanking them "for [their] time this AM." Ex. 26 at 1. In the email, Dr. Sweeney noted that, during the presentation, he had "forgot[ten] to mention how [his] IP affects your PFNA augmented products." *Id.* DePuy's "PFNA augmented products" were products highly similar to the TFNA products; however, on information and belief, the PFNA augmented products were never sold in the United States—they were only sold in Europe. *See, e.g.,* Ex. 27 (PFNA Surgical Technique Guide) at 4, 8-9 (showing similarity between PFNA and TFNA) and 104 ("This publication is not intended for distribution in the USA.") Thus, by advising senior J&J / DePuy executives that his IP, including the Patents-in-Suit, affected the "PFNA augmented products," Dr. Sweeney advised DePuy and J&J that his IP, including the Patents-in-Suit, affected the highly similar TFNA products.

64. In particular, Dr. Sweeney's email noted that DePuy's "British division was notified a few years ago as to the existence of [SG's] British, German and French patents but they never responded." Ex. 26 at 1. There, Dr. Sweeney was referring to a letter that his UK patent attorneys, Potter Clarkson LLP, had sent to "Synthes Ltd" in Hertfordshire, UK on March 29, 2012. *See* Ex. 28 (3/29/2012 Potter Clarkson letter); *see also* Ex. 29 (Certificate of Posting, confirming delivery of the 3/29/2012 letter). In the letter, Potter Clarkson noted that its "client, Spinal Generations, LLC, has asked us to notify you of the existence of its European patent, EP 1 653 869 B1." Ex. 28 at 1. The letter also "enclose[d] a copy of the patent." *Id.*

65. A copy of the European Patent, EP 1 653 869 ("EP '869"), is attached as Exhibit 30 hereto. The first page of EP '869 notes that it claims priority to three US patent applications, including "US 620287," which is the application for the '572 patent, and "US 704526," which is the application for the '611 patent. Ex. 30 at 1. Moreover, the disclosure of EP '869 is essentially

the same as the disclosure of the '611 and '337 patents. Thus, by advising DePuy of the European EP '869 patent, Dr. Sweeney also advised DePuy of the U.S. Patents-in-Suit.

66. In his April 17, 2015 email, Dr. Sweeney advised J&J and DePuy that he was "reluctan[t] to give exclusivity" to the Patents-in-Suit, "after the long fight to get this far." Ex. 26 at 1. He stated that the patented approach was "the way orthopedics will be done in the future and that needs to be recognized by any partner." *Id.* Nonetheless, he stated, "[i]f there is interest on your part, there is certainly potential for DePuy Synthes to be my corporate partner." *Id.*

67. Shortly after the meeting, Mr. Pachuda emailed Dr. Sweeney to praise him on his "impressive progress in multiple areas." Ex. 39 (Email, Pachuda to Sweeney, 4/17/2015). He stated that DePuy was "circling back as a team to discuss these opportunities," and "hope[d] to get back to [Dr. Sweeney] in the next week or so." *Id.*

68. DePuy did not respond in the next week or so. On May 14, 2015, Dr. Sweeney emailed Dr. Serhan, noting "[t]here has ben no communication since [the presentation] and [he] was wondering if that is a sign of disinterest?" Ex. 40 (Email, Sweeney to Serhan, 5/14/2015).

69. Dr. Sweeney did not receive a response for another two months. Finally, on July 22, 2015, Mr. Pachuda responded, apologizing for having not "closed the loop with you on Flow-FX." Ex. 41 (Email, Pachuda to Sweeney, 7/22/2015). Mr. Pachuda stated that J&J "did review all of your technologies across Spine, Trauma, and Biomaterials"—including Flow-Nail—but "were not interested in moving forward with discussions." *Id.*

70. Dr. Sweeney responded to Mr. Pachuda, that same day: "despite my thanks for the follow up, please know that ***none of our conversations, in any way, should be construed as giving DePuy Synthes license in regard to my US or EUROPEAN patents and IP***." Ex. 42 (Email, Sweeney to Pachuda, 7/22/2015). This put DePuy on clear, unambiguous notice that—if it

introduced an infringing product in the United States—SG could take legal action.

71. Dr. Sweeney reiterated his belief that the PFNA product infringed his European patents in a November 2015 email chain with Dr. Serhan. *See* Ex. 43 (Email chain, Sweeney and Serhan, November 2015). In the chain, Dr. Sweeney noted that he was "about to start a more involved relationship with your European folk." *Id.* Dr. Serhan responded, "are they interested in distributing your flow-fx device OUS [outside the US]?" *Id.* Dr. Sweeney responded: "No- they are marketing devices in a new manner that ***still conflict with my English, French and German patents***- starting down a road I was hoping to avoid. Their trauma needle combines with the implant ***to violate my patent***." *Id.* In support, Dr. Sweeney provided a link to DePuy's European website for the ***PFNA product***: the same product that is virtually indistinguishable from the TFNA product it later launched in the United States. *Id.* This put DePuy on clear notice that—if they introduced a PFNA-like product in the United States—it would infringe the Patents-in-Suit.

72. DePuy was undeterred. In October 2017, DePuy issued a press release touting the release of the "TFNA Augmentation System," which clearly infringed the Patents-in-Suit that Dr. Sweeney had extensively discussed with J&J and DePuy in 2014-2015. *See* Ex. 13; *see also* Counts 1, 4, 7, 10, 13 *infra.* Indeed, the TFNA Augmentation System was virtually indistinguishable from the European "PFNA augmented products" that Dr. Sweeney had told J&J and DePuy were infringing "[his] IP," including his "English, French and German patents" (EP '869)—which cover the same subject matter as, and list on their face, the U.S. Patents-in-Suit.

73. Accordingly, and on information and belief, DePuy introduced the TFNA Augmentation System in the United States with full knowledge of the Patents-in-Suit, and full knowledge that that system infringes the Patents-in-Suit.

JOINDER – 35 U.S.C. § 299

74. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-73 *supra* as if fully set forth herein.

75. Joinder of all Defendants is proper in this single action because: (i) SG's right to relief against the Defendants is asserted jointly, severally, or in the alternative; (ii) SG's right to relief against each Defendant arises out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process; and (iii) questions of fact common to all defendants will arise in the action. 35 U.S.C. § 299(a).

76. Although the precise role of each Defendant in making, selling, offering for sale, using, and importing the accused TFNA system in the United States is difficult to discern from public information, such information makes it clear that each Defendant does play a role in making, selling, offering for sale, importing, or using the TFNA products in the United States.

77. For instance, the TFNA Surgical Guide states that the TFNA system is "Manufactured or distributed by:" (i) "Synthes USA Products, LLC" (i.e., Defendant Synthes USA Products); and (ii) "Synthes USA, LLC" (i.e., Defendant Synthes USA). Ex. 7 at 116. Meanwhile, the same document bears a copyright notice stating: "© DePuy Synthes 2021." *Id.* Thus, DePuy's own document indicates all three Defendants have a role in making, selling, offering for sale, using, and/or importing the accused TFNA products in the United States.

78. The FDA's Establishment Registration and Device Listing database indicates that at least Defendants Synthes USA Products and Synthes USA are involved in designing, making, selling, offering for sale, using, or importing the accused TFNA products in the United States. *See* Ex. 31 (FDA database printout) at 2-3 (listing Synthes USA Products as a "Specification

Developer" and "Complaint File Establishment" for the TFNA products, and listing Synthes USA as a "Manufacturer" for the TFNA products). While the FDA database does not expressly identify Defendant DePuy Synthes as being involved in making or selling the accused TFNA products, on information and belief, DePuy Synthes—as the main "orthopaedics company of Johnson & Johnson" (Ex. 7 at 116)—does play an active role in making, selling, offering for sale, using, or importing accused TFNA products in the United States.

79. This is confirmed by the October 12, 2017 press release announcing the U.S. launch of the TFNA Augmentation System. That press release states that "Today ***DePuy Synthes**** announced the U.S. launch of the new TFNA Augmentation System." Ex. 13 at 1. The asterisk indicates that the term "DePuy Synthes represents ***the products and services of DePuy Synthes, Inc.*** and its subsidiaries." *Id.* at 2. Thus, the press release expressly indicates that Defendant DePuy Synthes, along with its subsidiaries, is directly involving in making, selling, offering for sale, using, or importing TFNA products in the United States.

80. SG's right to relief arises out of all three Defendants' "series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process," i.e., the TFNA product. Additionally, "questions of fact common to all defendants will arise in the action," including common questions relating to whether the TFNA product infringes the claims of the Patents-in-Suit.

81. Thus, joinder of all three Defendants is proper under 35 U.S.C. § 299(a).

PATENT MARKING – 35 U.S.C. § 287(a)

82. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-81 *supra* as if fully set forth herein.

83. On October 3, 2012, SG entered into a Patent License agreement with Flow-FX.

The license permitted Flow-FX to "make, have made, import, use, offer to sell and sell in the [United States] methods and devices to deliver medicine to bone as claimed in the" Patents-in-Suit. The license further provided: "Where feasible and practical, [Flow-FX] shall mark all Licensed Products sold under the provisions of this License with proper notice of patent or patent pending as prescribed under 35 U.S.C. § 287."

84. Flow-FX complied with that provision. Specifically, whenever Flow-FX sold a Flow-Nail product that practiced claims of a Patent-in-Suit in the United States, it provided proper notice of the relevant patent(s) in compliance with 35 U.S.C. § 287(a).

85. At all relevant times, Flow-FX included the legend "PAT http://flow-fx.net" on the instrument tray that is included with each Flow-Nail system, as shown below:

86. At all relevant times, the patent numbers of the Patents-in-Suit were listed at the URL http://flow-fx.net. For instance, an October 28, 2014 capture of http://flow-fx.net by the Wayback Machine (Ex. 32) shows that the "Flow Nail" section of the site included a link to

"Download [a] Sellsheet." Ex. 32. Upon clicking the link, a PDF document (Ex. 33) is displayed, which states that the Flow-Nail product is "Protected by US patents 7527611, 7575572, 7608062, 8062270," and by "US patents pending- 12/427520,13/270072, 13/227730, 13/569062."

87. Similarly, a January 25, 2017 capture of http://flow-fx.net by the Wayback Machine (Ex. 34) shows that the following issued and pending patents were listed on the website:

U.S. Patents

8,870,836
8,808,337
8,062,270
7,608,092
7,575,572
7,527,611

U.S. patents pending

14/864290
14/137092
14/081784
14/209302
13/569062
13/886945

EPO patents in the United Kingdom, Germany, France

EP1653869
EP2919680

88. Clicking on the "Information Sheet" for the Flow-Nail on the January 25, 2017 capture displays a PDF document (Ex. 35), which states that Flow-Nail is "patented (see www.flow-fx.net)," referring back to the patent listing on the website. Ex. 35 at 2.

89. The current flow-fx.net website continues to list the Patents-in-Suit: *see* https://flow-fx.net/products/ (Ex. 36), accessed on September 19, 2022:

U.S Patents

8,870,836	D773,926
8,808,337	9,510,841
8,062,270	9,517,075
7,608,092	D801,796
7,575,572	D831,475
7,527,611	D829,539
8,870,836	D830,820
9,445,852	10,335,218
9,603,644	10,188,440
9,949,777	9,282,975
9,833,272	9,833,272
9,282,975	9,603,644
9,615,863	9,949,777
10,188,446	

90. The flow-fx.net website, which has listed the patent numbers of the Patents-in-Suit in compliance with 35 U.S.C. § 287(a) at all relevant times, has always been, and continues to be, "accessible to the public without charge." 35 U.S.C. § 287(a).

91. The license that SG granted to Flow-FX is the only license SG has granted to others to practice the Patents-in-Suit. SG has not itself made, sold, offered for sale, or imported Flow-Nail products, or other products that practice the claims of the Patents-in-Suit.

92. In view of the foregoing, at all relevant times, SG's sole licensee for the Patents-in-Suit, Flow-FX, complied with the requirements of the marking statute, 35 U.S.C. § 287(a). Accordingly, the marking statute poses no bar to SG's recovery of damages in this case.

COUNT 1: DIRECT INFRINGEMENT OF THE '611 PATENT

93. SG repeats and re-alleges each of the allegations set forth in Paragraphs 1-92 *supra* as if fully set forth herein.

94. Defendants have directly infringed at least one claim of the '611 patent by making, selling, offering for sale, using, and/or importing in the United States the TFNA and Augmentation Systems (the "Accused Instrumentalities") during the lifetime of the '611 patent.

95. For example[1], claim 1 of the '611 patent recites:

> (1pre). A system for delivering a substance to a bone, the system comprising:
>
> (1a) a bone screw comprising two ends connected by a shaft, wherein the shaft is threaded along at least a portion of its exterior and cannulated along at least a portion of its length, and further wherein the bone-screw is threaded

[1] The specific patent claims identified in this Complaint are merely exemplary, not exhaustive. SG will provide its full list of the asserted claims at the appropriate time(s) under this Court's Default Standard for Discovery, the Local Rules, and the Scheduling Order.

along at least a portion of its interior;

(1b) one or more bone-screw fenestrations disposed along the cannulated portion of the bone-screw shaft;

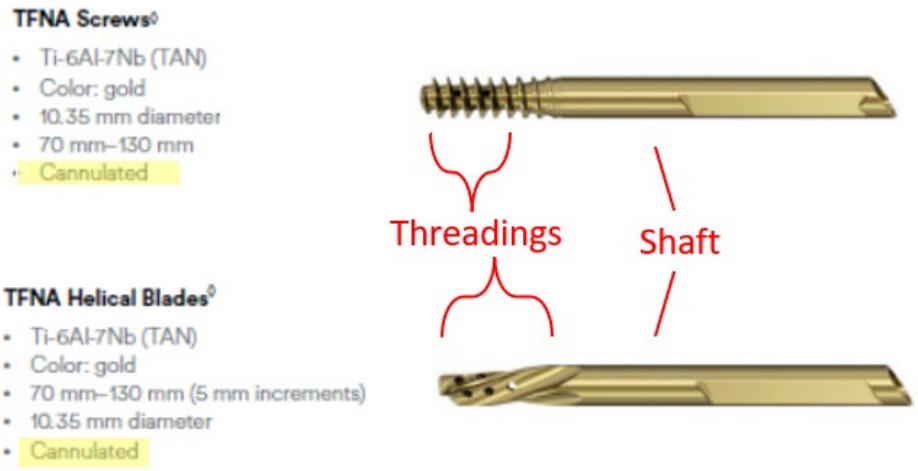
(1c) an insert disposed inside the bone-screw cannulation, wherein the insert is cannulated along at least a portion of its length, and further wherein the insert is threaded along at least a portion of its exterior and configured to interlock with the threaded portion of the bone-screw cannulation; and

(1d) one or more insert fenestrations disposed along the cannulated portion of the insert.

96. The Accused Instrumentalities satisfy each and every element of this claim, either literally or under the doctrine of equivalents:

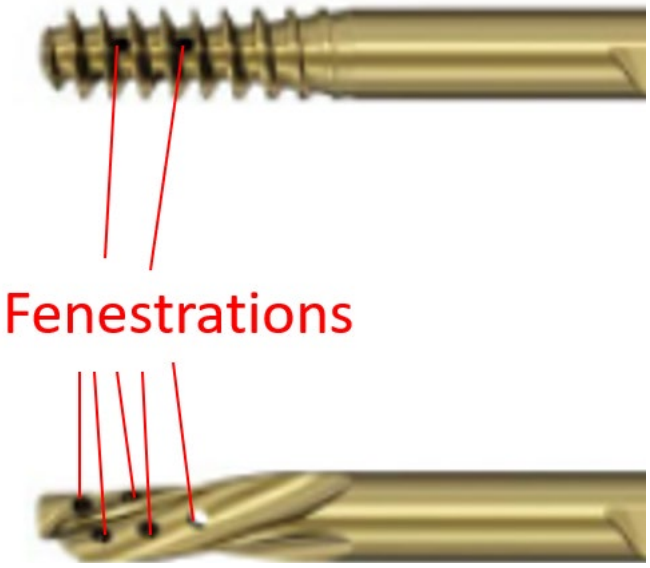
a. **(1pre):** To the extent the preamble is limiting (which SG does not concede), the Accused Instrumentalities are a "system" for delivering a "substance"—i.e., "PMMA bone cement" (Ex. 7 at 5)—to bone.

b. **(1a)**: The Accused Instrumentalities include a "bone screw"—i.e., the "helical blade or screw" that is inserted into the patient's bone (*id.* at 29); *id.* at 74:



As seen above, the helical blade and screw each comprise two ends connected by a shaft. Both shafts are threaded along at least a portion of their exterior. As indicated in highlighting above, Ex. 7 specifically states that the helical blade and screw are "cannulated" along at least a portion of their length. *Id.* The helical bland and screw are also threaded along at least a portion of their interior. *See, e.g.,* Ex. 7 at 31, 33. Thus, all parts of element (1a) are literally present in the Accused Instrumentalities.

c. **(1b):** The helical blade and screw each have one or more fenestrations disposed along the cannulated portion of the shaft (*id.* at 74):



Thus, all parts of element (1b) are literally present in the Accused Instrumentalities.

d. **(1c):** The Accused Instrumentalities include an "insert"—i.e., the side-opening cannula—which is "disposed inside the bone-screw cannulation" (*id.* at 47):

6. Insert side-opening cannula

Confirm that the selected length on the side-opening cannula corresponds with the length of the helical blade/screw.

Insert the side-opening cannula through the guide sleeve into the blade/screw until the stop.

Verify under image intensification that the side-opening cannula is fully inserted.

The side-opening cannula is cannulated along at least a portion of its length. *Id.* at 46. It is also threaded along at least a portion of its exterior (Ex. 7 at 40):

1. Adjust sleeve of side-opening cannula

Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

Adjust the sleeve of the side-opening cannula to the selected head element length. Length adjustments are made by turning the sleeve (2), while holding the handle of the side-opening cannula (1). One clockwise turn of the sleeve relates to 5 mm lateral axial movement of the side-opening cannula.

The side-port cannula is configured to interlock with the threaded portion of the bone-screw cannulation, in that the side-port cannula is designed to be inserted through the threaded portion of the bone-screw cannulation. *See id.* at 31, 33, 47. Thus, this element is literally present in the Accused Instrumentalities. Or, if it is

not literally present, it is present under the doctrine of equivalents, because the side-port cannula, sleeve, and bone-screw cannulation of the Accused Instrumentalities perform substantially the same function (guiding the insert to the proper location in the cannulation) in substantially the same way (threading) to achieve substantially the same result (proper insertion of the insert) as the claimed "insert … configured to interlock with the threaded portion of the bone-screw cannulation."

e. **(1d):** The side-opening cannula includes one or more insert fenestrations disposed along the cannulated portion of the insert (*id.* at 46):

Thus, all parts of element (1d) are literally present in the Accused Instrumentalities.

97. Because all elements of claim 1 of the '611 patent are literally or equivalently present in the Accused Instrumentalities, Defendants directly infringe that claim when they make, sell, offer for sale, use, or import the Accused Instrumentalities in the United States.

98. Based on publicly-available information, and on information and belief, Defendants have made, sold, offered for sale, used, and/or imported the Accused Instrumentalities in the United States during the lifetime of the Patents-in-Suit, including the '611 patent.

99. In October 2017, Defendants issued a press release touting the release of the Accused Instrumentalities in the United States. Ex. 13. In a 2018 presentation, Ciro Romer,

Company Group Chairman of DePuy for North America, touted "TFNA Augmentation" as part of DePuy's "Comprehensive Portfolio of Best-in-Class Products," (Ex. 37 (Romer presentation) at 21), and stated that DePuy had "[s]trong performance in core platforms with ***TFN-ADVANCED***." *Id.* at 28. In a January 2019 presentation, Christopher DelOrefice, J&J's Vice President of Investor Relations, noted that J&J's sales "growth" in "Trauma" was driven by "uptake of new products, ***primarily the TFN-ADVANCED nailing system*** coupled with market growth in the U.S." Ex. 38 (DelOrefice presentation) at 13. Thus, it is clear that Defendants enjoyed substantial U.S. sales of the Accused Instrumentalities during the lifetime of the Patents-in-Suit, including the '611 patent, constituting direct infringement of at least claim 1 of that patent.

100. In addition to sales and offers to sell, on information and belief, Defendants also made Accused Instrumentalities in the United States during the lifetime of the Patents-in-Suit, including the '611 patent. For instance, on information and belief, Defendants made Accused Instrumentalities in the United States by manufacturing one or more of the components thereof in the United States, and/or by assembling Accused Instrumentalities—such as by inserting a side-opening cannula into a helical blade or screw—in the United States. Such making of Accused Instrumentalities in the United States constituted direct infringement of claims of the Patents-in-Suit, including claim 1 of the '611 patent.

101. On information and belief, Defendants also used Accused Instrumentalities in the United States during the lifetime of the Patents-in-Suit, including the '611 patent. For instance, on information and belief, Defendants used the Accused Instrumentalities in the United States in connection with internal testing and research and development. On information and belief, Defendants also used the Accused Instrumentalities in the United States in connection with product demonstrations, training, marketing, advertising, and physician outreach. Such use of Accused

Instrumentalities in the United States constituted direct infringement of claims of the Patents-in-Suit, including claim 1 of the '611 patent.

102. Accordingly, under 35 U.S.C. § 271(a), Defendants are liable to SG for their past, present, and ongoing direct infringement of the '611 patent.

COUNT 2: INDUCED INFRINGEMENT OF THE '611 PATENT

103. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-102 *supra* as if fully set forth herein.

104. Defendants have unlawfully induced infringement of at least one claim of the '611 patent by selling the Accused Instrumentalities to U.S. customers, and expressly instructing such customers on how to make and use the Accused Instrumentalities in an infringing manner, all while knowing of the '611 patent, and knowing (or being willfully blind) that making or using the Accused Instrumentalities infringes at least one claim of the '611 patent.

105. As shown in Paragraphs 96-97 *supra*, when the side-port cannula of the TFNA Augmentation System is inserted into the cannula of a TFNA helical blade or screw, the resulting assembly is a "system" that satisfies all elements of at least claim 1 of the '611 patent. Accordingly, when Defendants' end-users—i.e., surgeons—insert the side-port cannula into the helical blade or screw, they "make" a "system" that satisfies all the elements of at least claim 1 of the '611 patent. Such making constitutes direct infringement of at least claim 1 of the '611 patent.

106. Moreover, when Defendants' end-users—i.e., surgeons—actually use the side port cannula / helical blade or screw assembly to deliver PMMA bone cement to a patient's bone, they are "using" a system that satisfies all elements of at least claim 1 of the '611 patent. Such use constitutes direct infringement of at least claim 1 of the '611 patent.

107. Accordingly, Defendants' end-users—i.e., surgeons—directly infringe at least

claim 1 of the '611 patent when they assemble and use the Accused Instrumentalities in the manner specifically intended and directed by Defendants in the United States.

108. Defendants provide extensive instruction and assistance to their end-users, explicitly instructing them on how to use the Accused Instrumentalities in an infringing way. For instance, Defendants provide end-users with the 117-page "TFN-Advanced Surgical Technique" guide (Ex. 7). The guide provides over sixty pages of detailed, step-by-step instructions on how to use the Accused Instrumentalities in an infringing manner. Ex. 7 at 8-68. As shown in Paragraph 47 *supra*, the Surgical Technique Guide specifically instructs surgeons on each step required to assemble and use the Accused Instrumentalities, including insertion of the nail and helical screw or blade, preparation and prefilling of the side-port cannula, insertion of the side-port cannula, and use of the side-port cannula to deliver PMMA cement to bone. *Id.* at 18-50. As shown in Paragraph 96 *supra*, when surgeons follow the instructions set forth in the Surgical Technique Guide, they both "make" and "use" a system that practices all the elements of at least claim 1 of the '611 patent. Accordingly, by providing the Surgical Technique Guide to end-users, Defendants committed (and continue to commit) acts that induce end-user surgeons to commit direct infringement of at least claim 1 of the '611 patent.

109. In addition to the Surgical Technique Guide, Defendants provide "Instructions for Use," which further instruct end-users on how to use the Accused Instrumentalities in an infringing manner. *See* https://www.jnjmedtech.com/en-US/product/tfn-advanced-proximal-femoral-nailing-system-tfna. Defendants also provide, on their website, a thirteen-minute video showing, on a step-by-step basis, how to use the Accused Instrumentalities in an infringing manner. *Id.* Defendants' provision of these materials constitutes further acts that induce end-user surgeons to commit direct infringement of at least claim 1 of the '611 patent.

110. On information and belief, Defendants also provide hands-on assistance and training to end-user surgeons, showing them how to use the Accused Instrumentalities in their intended fashion. Such hands-on assistance and training constitutes further acts that induce end-user surgeons to commit direct infringement of at least claim 1 of the '611 patent.

111. When Defendants committed the inducing acts described above, they were aware of the Patents-in-Suit. As shown in Paragraphs 63-65 *supra*, Defendants have been aware of the Patents-in-Suit since at least March 2012, when SG's UK patent counsel sent a copy of the EP '869 patent—which lists the applications for the '611 and '572 patents on its face—to Defendants. Defendants were further advised of the Patents-in-Suit when Dr. Sweeney emailed copies of the '611 and '572 patents—and the Docket Report listing all other pending and issued patents at the time—to Defendants' U.S. sales representative in January 2014. *See* Paragraph 56 *supra*. Defendants were advised of the Patents-in-Suit yet again in April 2015, when Dr. Sweeney delivered a presentation about Flow-Nail and the Patents-in-Suit to several high-ranking officers of Defendants. *See* Paragraphs 57-66. Thus, Defendants were well-aware of the Patents-in-Suit, including the '611 patent, before they began committing the inducing acts complained of above (i.e., before the October 2017 U.S. launch of the Accused Instrumentalities).

112. On information and belief, when Defendants committed the inducing acts complained of above, they also knew—or else were willfully blind—that their end-users' assembly and use of the Accused Instrumentalities infringed at least one claim of the Patents-in-Suit, including at least one claim of the '611 patent. During his April 2015 communications with Defendants, Dr. Sweeney specifically advised them that his patents covered the "PFNA augmented" product being sold in Europe. *See* Paragraphs 63, 70-71 *supra*. The Accused Instrumentalities are virtually indistinguishable from the PFNA augmented products, which

Defendants—the designers of both products—would have known. *Id.* Indeed, Dr. Sweeney specifically advised Defendants that "none of our conversations, in any way, should be construed as giving DePuy Synthes license in regard to my US or EUROPEAN patents and IP," and that the PFNA product "conflict[s] with my English, French and German patents." Paragraphs 70-71 *supra.* Thus, because Defendants knew that the PFNA product infringed claims of the Patents-in-Suit, they knew—or else were willfully blind—that the substantially similar Accused Instrumentalities also infringed claims of the Patents-in-Suit, including the '611 patent.

113. Moreover, in April 2015, Dr. Sweeney extensively discussed his Flow-Nail product with several high-level executives of Defendants, stressing that that product was protected by his "IP" (the Patents-in-Suit). *See* Paragraphs 57-73 *supra*. The Flow-Nail product is remarkably similar to the "PFNA augmented" system and to the Accused Instrumentalities—which Defendants would have known. Accordingly, on information and belief, Defendants further knew that the Accused Instrumentalities infringed at least one claim of the Patents-in-Suit, including the '611 patent, because they knew that the Accused Instrumentalities were substantially similar to the Flow-Nail product protected by the Patents-in-Suit—or, if not, they were willfully blind as to the likelihood of such infringement.

114. Therefore, for the foregoing reasons, Defendants are liable to SG for induced infringement of the '611 patent under 35 U.S.C. § 271(b).

COUNT 3: CONTRIBUTORY INFRINGEMENT OF THE '611 PATENT

115. SG repeats and realleges each and every allegation set forth in Paragraphs 1-114 *supra* as if fully set forth herein.

116. Defendants have unlawfully contributed to infringement of the '611 patent by making, selling, and distributing the Accused Instrumentalities in the United States, where the

Accused Instrumentalities constitute a material part of the claimed invention, where Defendants knew the Accused Instrumentalities were especially adapted for use in infringement of the '611 patent, and where the Accused Instrumentalities are not staple articles or commodities of commerce suitable for substantial non-infringing use.

117. As shown in Paragraphs 96-97 *supra*, when the side-port cannula of the TFNA Augmentation System is inserted into the cannula of a TFNA helical blade or screw, the resulting assembly is a "system" that satisfies all elements of at least claim 1 of the '611 patent. Accordingly, when Defendants' end-users—i.e., surgeons—insert the side-port cannula into the helical blade or screw, they "make" a "system" that satisfies all the elements of at least claim 1 of the '611 patent. Such making constitutes direct infringement of at least claim 1 of the '611 patent.

118. When Defendants' end-users—i.e., surgeons—actually use the side port cannula / helical blade or screw assembly to deliver PMMA bone cement to a patient's bone, they are "using" a system that satisfies all elements of at least claim 1 of the '611 patent. Such use constitutes direct infringement of at least claim 1 of the '611 patent.

119. Accordingly, Defendants' end-users—i.e., surgeons—directly infringe at least claim 1 of the '611 patent when they assemble and use the Accused Instrumentalities in the manner specifically intended and directed by Defendants in the United States.

120. Since October 2017, Defendants have continually sold and offered to sell the Accused Instrumentalities to end-users in the United States. *See* Paragraphs 98-99 *supra*.

121. The Accused Instrumentalities sold by Defendants are components of the system claimed in at least claim 1 of the '611 patent, and constitute a material part of the claimed invention. Indeed, the Accused Instrumentalities include ***every*** part of the invention claimed in at least claim 1 of the '611 patent. All an end-user must do to make the system claimed in claim 1 of

the ‘611 patent is take the Accused Instrumentalities supplied by Defendants, and assemble them in the way specifically intended and directed by Defendants.

122. As shown in Paragraphs 51-73 *supra*, Defendants knew—or else were willfully blind—that their end-users’ ordinary assembly and use of the Accused Instrumentalities constitutes direct infringement of at least claim 1 of the ‘611 patent. Thus, Defendants knew that the Accused Instrumentalities were especially adapted for use in an infringement of the ‘611 patent.

123. Finally, the Accused Instrumentalities are not staple articles of commerce suitable for substantial non-infringing use. Rather, the ***only*** substantial use of the Accused Instrumentalities is to assemble and use them in the manner intended and directed by Defendants, which constitutes direct infringement of at least claim 1 of the ‘611 patent.

124. Accordingly, for the foregoing reasons, Defendants are liable to SG for contributory infringement of the ‘611 patent in violation of 35 U.S.C. § 271(c).

COUNT 4: DIRECT INFRINGEMENT OF THE ‘572 PATENT

125. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-124 *supra* as if fully set forth herein.

126. Defendants have directly infringed at least one claim of the ‘572 patent by making, selling, offering for sale, using, and/or importing in the United States the Accused Instrumentalities during the lifetime of the ‘572 patent.

127. For example, claim 1 of the ‘572 patent recites:

> (1pre). A device for delivering a substance to a bone, the device comprising:
>
> (1a) a bone screw comprising two ends connected by a shaft, wherein the shaft is cannulated along at least a portion of its length;

(1b) one or more bone-screw fenestrations disposed along the cannulated portion of the bone-screw shaft;

(1c) an insert disposed inside the cannulated bone-screw shaft, wherein the insert comprises two ends connected by a shaft and is cannulated along at least a portion of its length; and

(1d) one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert,

(1e) wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations; and a second position wherein the insert provides a delivery pathway for the substance between at least one end of the bone screw and the at least one bone-screw fenestration.

128. The Accused Instrumentalities literally satisfy each and every element of this claim:

a. **(1pre)**: To the extent the preamble is limiting (which SG does not concede), the Accused Instrumentalities are a "device" for delivering a "substance"—i.e., "PMMA bone cement" (Ex. 7 at 5)—to bone.

b. **(1a)** This element, directed to the "bone screw," is broader than corresponding element (1a) of the '611 patent. Thus, this element is literally satisfied by the Accused Instrumentalities for the reasons set forth in Paragraph 96(b) *supra*.

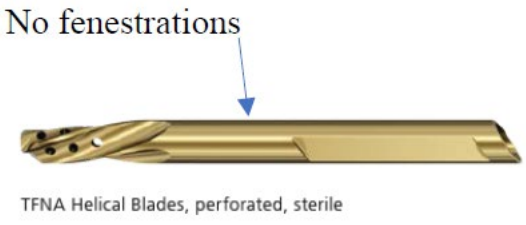
c. **(1b)**: The element is identical to element 1(b) of the '611 patent. Thus, this element is literally satisfied by the Accused Instrumentalities for the reasons set

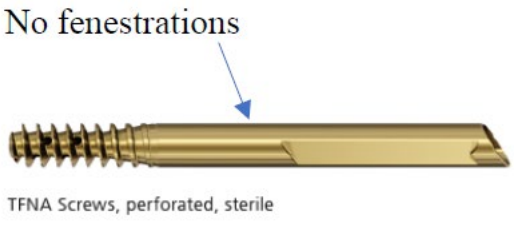
forth in Paragraph 96(c) *supra*.

d. **(1c)**: As shown in Paragraph 96(d) *supra*, the side-opening cannula of the Accused Instrumentalities is an insert disposed inside the cannulated shaft of the helical blade or screw. Ex. 7 at 47. The side-opening cannula comprises two ends connected by a shaft, and is cannulated along at least a portion of its length. *Id.* at 40, 46-47. Accordingly, all parts of this element are literally present in the Accused Instrumentalities.

e. **(1d):** The side-opening cannula includes one or more insert fenestrations disposed along the cannulated portion of the insert, between the two ends of the insert. *See id.* at 46. Thus, all parts of this element are literally present in the Accused Instrumentalities.

f. **(1e)**: The side-opening cannula is movable between multiple positions within the cannulated portion of the helical blade or screw. Specifically, "[o]ne clockwise turn of the sleeve relates to 5 mm lateral axial movement of the side opening cannula." *Id.* at 40. Thus, by rotating the sleeve clockwise or counter-clockwise, the user can move the fenestration of the side-opening cannula to different positions within the helical blade or screw. Meanwhile, the helical blade and screw each contain a portion of their length with no fenestrations:





When the user positions the fenestration of the side-opening cannula at one of

the positions with no fenestrations, the fenestration is blocked, such that none of the one or more insert fenestrations align with the one or more bone-screw fenestrations, and at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations. In such a position, the side-opening cannula is in a "first position" of the claim. When the user rotates the side-opening cannula to align its fenestration with one or more of the fenestrations in the helical blade or screw, the side-opening cannula is in a "second position," in which it provides a delivery pathway for the PMMA bone cement to flow between at least one end of the helical blade or screw and at least one fenestration in the helical blade or screw. Accordingly, all parts of this element are literally present in the Accused Instrumentalities.

129. Because all elements of claim 1 of the '572 patent are literally present in the Accused Instrumentalities, Defendants directly infringe that claim when they make, sell, offer for sale, use, or import the Accused Instrumentalities in the United States.

130. As shown in Paragraphs 98-101 *supra*, Defendants directly infringed (and continue to directly infringe) at least claim 1 of the '572 patent by making, selling, offering for sale, importing, and/or using the Accused Instrumentalities in the United States during the life of the '572 patent. Accordingly, under 35 U.S.C. § 271(a), Defendants are liable to SG for their past, present, and ongoing direct infringement of the '572 patent.

COUNT 5: INDUCED INFRINGEMENT OF THE '572 PATENT

131. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-130 *supra* as if fully set forth herein.

132. Defendants have unlawfully induced infringement of at least one claim of the '572 patent by selling the Accused Instrumentalities to U.S. customers, and expressly instructing such customers on how to make and use the Accused Instrumentalities in an infringing manner, all while knowing of the '572 patent, and knowing (or being willfully blind) that making or using the Accused Instrumentalities infringes at least one claim of the '572 patent.

133. As shown in Paragraphs 128-129 *supra*, when the side-port cannula of the TFNA Augmentation System is inserted into the cannula of a TFNA helical blade or screw, the resulting assembly is a "device" that satisfies all elements of at least claim 1 of the '572 patent. Accordingly, when Defendants' end-users—i.e., surgeons—insert the side-port cannula into the helical blade or screw, they "make" a "device" that satisfies all the elements of at least claim 1 of the '572 patent. Such making constitutes direct infringement of at least claim 1 of the '572 patent.

134. Moreover, when Defendants' end-users—i.e., surgeons—actually use the side port cannula / helical blade or screw assembly to deliver PMMA bone cement to a patient's bone, they are "using" a device that satisfies all elements of at least claim 1 of the '572 patent. Such use constitutes direct infringement of at least claim 1 of the '572 patent.

135. Accordingly, Defendants' end-users—i.e., surgeons—directly infringe at least claim 1 of the '572 patent when they assemble and use the Accused Instrumentalities in the manner specifically intended and directed by Defendants in the United States.

136. As shown in Paragraphs 108-110 *supra*, Defendants provide extensive documentation and hands-on assistance to their end-customers, showing them how to use the Accused Instrumentalities in an infringing manner. Defendants' provision of such documentation and hands-on assistance constitutes inducing acts that induce end-users to commit direct infringement of at least claim 1 of the '572 patent.

137. As shown in Paragraphs 111-114 *supra*, Defendants were aware of the Patents-in-Suit, including the '572 patent, when they committed the inducing acts complained of above. As shown in Paragraphs 111-114 *supra*, Defendants were also aware—or else were willfully blind—that its end-users' assembly and use of the Accused Instrumentalities directly infringes at least one claim of the Patents-in-Suit, including the '572 patent.

138. Therefore, for the foregoing reasons, Defendants are liable to SG for induced infringement of the '572 patent under 35 U.S.C. § 271(b).

COUNT 6: CONTRIBUTORY INFRINGEMENT OF THE '572 PATENT

139. SG repeats and realleges each and every allegation set forth in Paragraphs 1-138 *supra* as if fully set forth herein.

140. Defendants have unlawfully contributed to infringement of the '572 patent by making, selling, and distributing the Accused Instrumentalities in the United States, where the Accused Instrumentalities constitute a material part of the claimed invention, where Defendants knew the Accused Instrumentalities were especially adapted for use in infringement of the '572 patent, and where the Accused Instrumentalities are not staple articles or commodities of commerce suitable for substantial non-infringing use.

141. As shown in Paragraphs 128-129 *supra,* Defendants' end-users—i.e., surgeons—directly infringe at least claim 1 of the '572 patent when they assemble and use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

142. Since October 2017, Defendants have continually sold and offered to sell the Accused Instrumentalities to end-users in the United States. *See* Paragraphs 98-99 *supra.*

143. The Accused Instrumentalities sold by Defendants are components of the system claimed in at least claim 1 of the '572 patent, and constitute a material part of the claimed

invention. Indeed, the Accused Instrumentalities include ***every*** part of the invention claimed in at least claim 1 of the '572 patent. All an end-user must do to make the device claimed in claim 1 of the '572 patent is take the Accused Instrumentalities supplied by Defendants, and assemble them in the way specifically intended and directed by Defendants.

144. As shown in Paragraphs 51-73 *supra*, Defendants knew—or else were willfully blind—that their end-users' ordinary assembly and use of the Accused Instrumentalities constitutes direct infringement of at least claim 1 of the '572 patent. Thus, Defendants knew that the Accused Instrumentalities were especially adapted for use in an infringement of the '572 patent.

145. The Accused Instrumentalities are not staple articles of commerce suitable for substantial non-infringing use. Rather, the ***only*** substantial use of the Accused Instrumentalities is to assemble and use them in the manner intended and directed by Defendants, which constitutes direct infringement of at least claim 1 of the '572 patent.

146. Accordingly, for the foregoing reasons, Defendants are liable to SG for contributory infringement of the '572 patent in violation of 35 U.S.C. § 271(c).

COUNT 7: DIRECT INFRINGEMENT OF THE '270 PATENT

147. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-146 *supra* as if fully set forth herein.

148. Defendants have directly infringed at least one claim of the '270 patent by making, selling, offering for sale, using, and/or importing in the United States the Accused Instrumentalities during the lifetime of the '270 patent.

149. For example, claim 1 of the '270 patent recites:

(1pre). A system for implantation within a bone comprising:

(1a) an insert comprising:

(1a1) a first end; a second end; a shaft connecting the first and second ends, wherein the shaft defines a cannulation extending along at least a portion of the length of the shaft; and

.(1a2) a seal coupled to the insert shaft, the seal having an inner surface facing the cannulation of the insert shaft, wherein the seal is configured to provide access to the cannulation following implantation of the system within the bone, and wherein the seal is configured to self-seal after access is provided to the cannulation;

(1a3) an opening located through the first end of the insert shaft, wherein the seal comprises an end cap including an outer surface contacting a surface of the insert to directly couple the end cap to the insert shaft such that the end cap seals the opening; and

(1a4) a fenestration disposed along the cannulated portion of the insert shaft, wherein the cannulation provides a delivery pathway for a substance between the opening and the fenestration; and

(1b) a bone screw comprising two ends connected by a shaft, wherein the insert is received by the bone screw, wherein the bone screw shaft is cannulated, wherein the insert is received within the bone screw cannulation

(1c) and the insert is movable between: a first position wherein a surface of the bone screw blocks the insert fenestration preventing the substance from exiting the cannulated portion of the insert via the insert fenestration; and a second position wherein the insert provides a delivery pathway for the substance between at least one end of the insert and a portion of the bone.

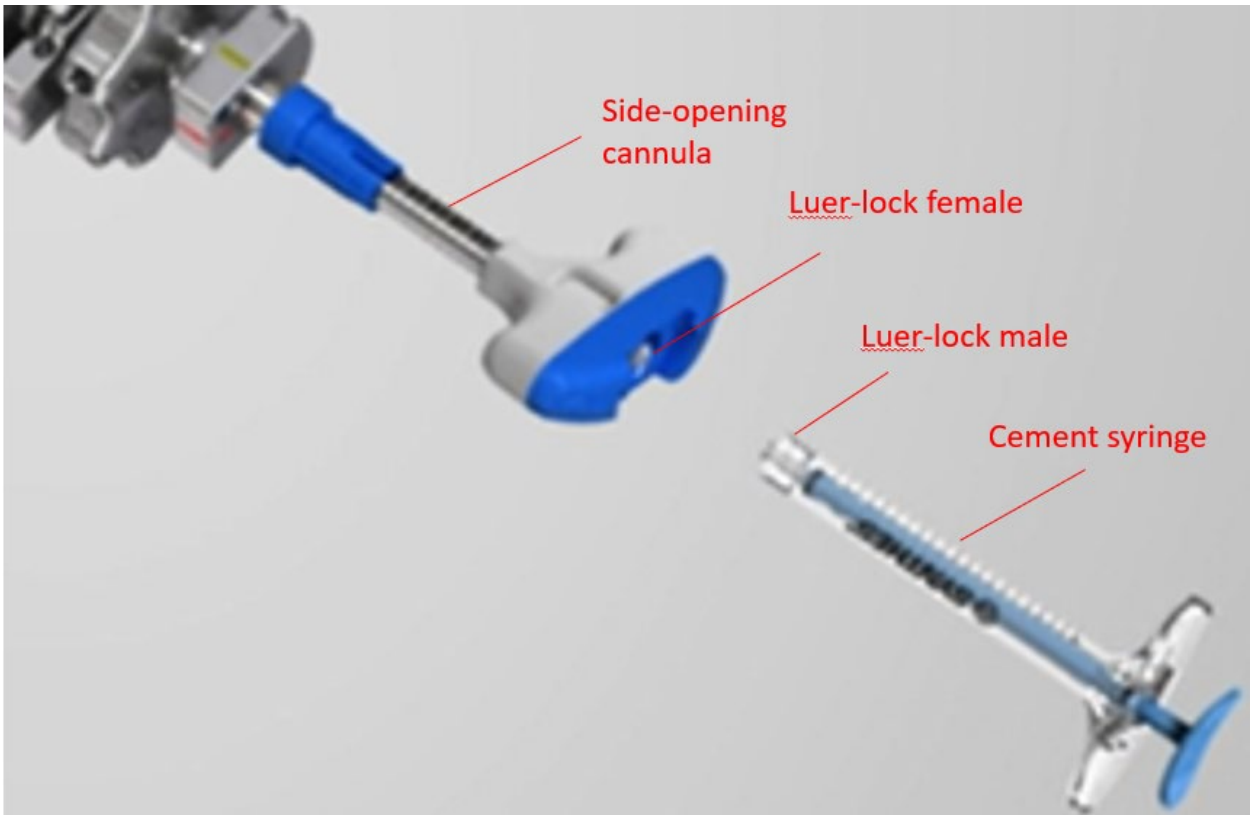
150. The Accused Instrumentalities satisfy every element of this claim, either literally or under the doctrine of equivalents.

a. **(1pre):** To the extent the preamble is limiting, which SG does not concede, the Accused Instrumentalities are a "system for implantation within a bone."

b. **(1a):** The Accused Instrumentalities include an "insert," i.e., the "side-opening cannula, with Luer-lock." Ex. 7 at 79.

c. **(1a1)**: The side-opening cannula includes a "first end" (the end that receives the syringes), a "second end" (the end opposite the first end), and a shaft connecting the first and second ends, where the shaft defines a cannulation extending along at least a portion of the length of the shaft. *Id.* at 46. Thus, all parts of this element are literally present in the Accused Instrumentalities.

d. **(1a2):** The Accused Instrumentalities have a "Luer-lock" mechanism which is a "seal coupled to the insert shaft." Ex. 7 at 79. On information and belief, and based on documentation and videos produced by Defendants, the female part of the Luer-lock mechanism is located at the proximal end of the side-opening cannula (the end that receives the syringes), and the male part of the Luer-lock mechanism is located at the distal end of the cement syringe, as shown below (annotated image taken from video posted at https://www.jnjmedtech.com/en-US/product/tfn-advanced-proximal-femoral-nailing-system-tfna):



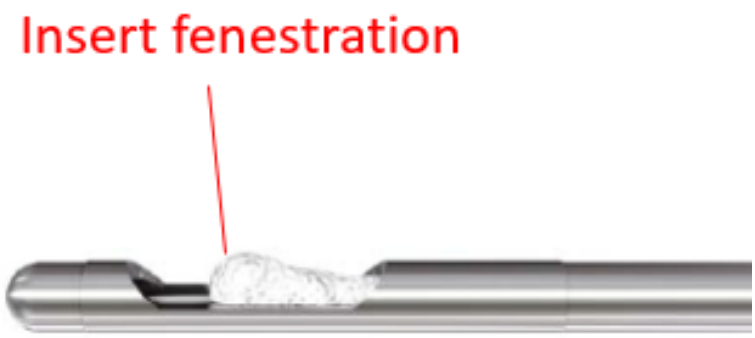
The Luer-lock mechanism has an "inner surface facing the cannulation of the insert shaft," i.e., the surface of the female part of the Luer-lock mechanism. The Luer-lock mechanism is "configured to provide access to the cannulation following implantation of the system within the bone," in that the Luer-lock allows cement to flow from the syringe into the side-opening cannula after the side-opening cannula is inserted into the bone. And the Luer-lock mechanism is "configured to self-seal after access is provided to the cannulation," in that when the male and female parts of the mechanism are engaged—i.e., after access has been provided to the cannulation for the cement within the syringe—the mechanism "self-seals," preventing cement leakage. Therefore, all parts of this element are literally present in the Accused Instrumentalities. Or, if they are not

literally present, the Accused Instrumentalities' Luer-lock mechanism satisfies this element under the doctrine of equivalents, because it performs substantially the same function (sealing the end of the insert), in substantially the same way (by mechanically blocking the end of the insert), to achieve substantially the same result (preventing cement from leaking out of the end of the insert).

e. **(1a3)**: The side-opening cannula includes an opening located through the first end of the insert shaft, i.e., the opening through which cement flows from the syringe into the side-opening cannula. The Accused Instrumentalities' Luer-lock mechanism (i.e., the "seal") further includes an end cap—i.e., the male part of the Luer-lock mechanism—which includes an outer surface that contacts a surface of the insert (i.e., the female part of the Luer-lock mechanism) to directly couple the end cap to the insert shaft such that the end cap seals the opening. Thus, all parts of this element are literally present in the Accused Instrumentalities. Or, if they are not literally present, the Accused Instrumentalities' Luer-lock mechanism satisfies this element under the doctrine of equivalents, because it performs substantially the same function (sealing the opening in the insert) in substantially the same way (by mechanically blocking the opening) to achieve substantially the same result (preventing cement from leaking out of the opening).

f. **(1a4)**: The side-opening cannula of the Accused Instrumentalities (i.e., the "insert") has a fenestration disposed along the cannulated portion of the insert shaft, wherein the cannulation provides a delivery pathway for a substance (i.e.,

PMMA cement) between the opening and the fenestration (Ex. 7 at 46):



Thus, all parts of this element are literally present in the Accused Instrumentalities.

g. **(1b):** The Accused Instrumentalities include a bone screw (i.e., the helical blade or screw) comprising two ends connected by a shaft. Ex. 7 at 74. The "insert" of the Accused Instrumentalities (i.e., the side-opening cannula) is received by the helical blade or screw. *Id.* at 47. The helical blade or screw is "cannulated." *Id.* at 74. And the side-opening cannula is received within the cannulation in the helical blade or screw. *Id.* at 47. Accordingly, all parts of this element are literally present in the Accused Instrumentalities.

h. **(1c):** This element is substantially the same as element (1e) of claim 1 of the '572 patent discussed *supra*. Accordingly, for the same reasons discussed as to that element in Paragraph 128(f) *supra*, this element is literally satisfied by the Accused Instrumentalities.

151. Because all elements of claim 1 of the '270 patent are present in the Accused Instrumentalities, either literally or by equivalents, Defendants directly infringe that claim when they make, sell, offer for sale, use, or import the Accused Instrumentalities in the United States.

152. As shown in Paragraphs 98-101 *supra*, Defendants directly infringed (and continue

to directly infringe) at least claim 1 of the '270 patent by making, selling, offering for sale, importing, and/or using the Accused Instrumentalities in the United States during the life of the '270 patent. Accordingly, under 35 U.S.C. § 271(a), Defendants are liable to SG for their past, present, and ongoing direct infringement of the '270 patent.

COUNT 8: INDUCED INFRINGEMENT OF THE '270 PATENT

153. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-152 *supra* as if fully set forth herein.

154. Defendants have unlawfully induced infringement of at least one claim of the '270 patent by selling the Accused Instrumentalities to U.S. customers, and expressly instructing such customers on how to make and use the Accused Instrumentalities in an infringing manner, all while knowing of the '270 patent, and knowing (or being willfully blind) that making or using the Accused Instrumentalities infringes at least one claim of the '270 patent.

155. As shown in Paragraphs 150-151 *supra*, when the side-port cannula of the TFNA Augmentation System is inserted into the cannula of a TFNA helical blade or screw, the resulting assembly is a "system" that satisfies all elements of at least claim 1 of the '270 patent. Accordingly, when Defendants' end-users—i.e., surgeons—insert the side-port cannula into the helical blade or screw, they "make" a "system" that satisfies all the elements of at least claim 1 of the '270 patent. Such making constitutes direct infringement of at least claim 1 of the '270 patent.

156. Moreover, when Defendants' end-users—i.e., surgeons—actually use the side port cannula / helical blade or screw assembly to deliver PMMA bone cement to a patient's bone, they are "using" a system that satisfies all elements of at least claim 1 of the '270 patent. Such use constitutes direct infringement of at least claim 1 of the '270 patent.

157. Accordingly, Defendants' end-users—i.e., surgeons—directly infringe at least

claim 1 of the ‘270 patent when they assemble and use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

158. As shown in Paragraphs 108-110 *supra*, Defendants provide extensive documentation and hands-on assistance to their end-customers, showing them how to make and use the Accused Instrumentalities in an infringing manner. Defendants’ provision of such documentation and hands-on assistance constitutes inducing acts that induce end-users to commit direct infringement of at least claim 1 of the ‘270 patent.

159. As shown in Paragraphs 111-114 *supra*, Defendants were aware of the Patents-in-Suit, including the ‘270 patent, when they committed the inducing acts complained of above. As shown in Paragraphs 111-114 *supra*, Defendants were also aware—or else were willfully blind—that its end-users’ assembly and use of the Accused Instrumentalities directly infringes at least one claim of the Patents-in-Suit, including the ‘270 patent.

160. Therefore, for the foregoing reasons, Defendants are liable to SG for induced infringement of the ‘270 patent under 35 U.S.C. § 271(b).

COUNT 9: CONTRIBUTORY INFRINGEMENT OF THE ‘270 PATENT

161. SG repeats and realleges each and every allegation set forth in Paragraphs 1-160 *supra* as if fully set forth herein.

162. Defendants have unlawfully contributed to infringement of the ‘270 patent by making, selling, and distributing the Accused Instrumentalities in the United States, where the Accused Instrumentalities constitute a material part of the claimed invention, where Defendants knew the Accused Instrumentalities were especially adapted for use in infringement of the ‘270 patent, and where the Accused Instrumentalities are not staple articles or commodities of commerce suitable for substantial non-infringing use.

163. As shown in Paragraphs 150-151 *supra,* Defendants' end-users—i.e., surgeons—directly infringe at least claim 1 of the '270 patent when they assemble and use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

164. Since October 2017, Defendants have continually sold and offered to sell the Accused Instrumentalities to end-users in the United States. *See* Paragraphs 98-99 *supra.*

165. The Accused Instrumentalities sold by Defendants are components of the system claimed in at least claim 1 of the '270 patent, and constitute a material part of the claimed invention. Indeed, the Accused Instrumentalities include ***every*** part of the invention claimed in at least claim 1 of the '270 patent. All an end-user must do to make the device claimed in claim 1 of the '270 patent is take the Accused Instrumentalities supplied by Defendants, and assemble them in the way specifically intended and directed by Defendants.

166. As shown in Paragraphs 51-73 *supra*, Defendants knew—or else were willfully blind—that their end-users' ordinary assembly and use of the Accused Instrumentalities constitutes direct infringement of at least claim 1 of the '270 patent. Thus, Defendants knew that the Accused Instrumentalities were especially adapted for use in an infringement of the '270 patent.

167. The Accused Instrumentalities are not staple articles of commerce suitable for substantial non-infringing use. Rather, the ***only*** substantial use of the Accused Instrumentalities is to assemble and use them in the manner intended and directed by Defendants, which constitutes direct infringement of at least claim 1 of the '270 patent.

168. Accordingly, for the foregoing reasons, Defendants are liable to SG for contributory infringement of the '270 patent in violation of 35 U.S.C. § 271(c).

COUNT 10: DIRECT INFRINGEMENT OF THE '337 PATENT

169. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-168

supra as if fully set forth herein.

170. Defendants have directly infringed at least one claim of the '337 patent by making, selling, offering for sale, using, and/or importing the Accused Instrumentalities in the United States during the lifetime of the '337 patent.

171. For example, claim 1 of the '337 patent recites:

> (1pre). A system for delivering a substance to a bone, the system comprising:
>
> (1a) an insert comprising two ends connected by a shaft, wherein the shaft of the insert is cannulated along at least a portion of its length;
>
> (1b) an insert fenestration disposed along the cannulated portion of the insert; and
>
> (1c) a bone screw comprising two ends connected by a shaft and having an internal cannulation comprising a hollow cavity disposed inside at least part of the shaft, the bone screw adapted to receive the insert,
>
> (1d) wherein the insert is movable between: a first position wherein a surface of the bone screw blocks the insert fenestration preventing the substance from exiting the cannulated portion of the insert via the insert fenestration; and a second position wherein the insert provides a delivery pathway for the substance between at least one end of the insert and a portion of the bone.

172. The Accused Instrumentalities literally satisfy every element of this claim:

a. **(1pre)**: To the extent the preamble is limiting, which SG does not concede, the Accused Instrumentalities are a "system" for delivering a "substance"—i.e.,

PMMA bone cement" (Ex. 7 at 5)—to bone.

b. **(1a):** This element, directed to the "insert," is broader than element (1c) of claim 1 of the '572 patent, also directed to the "insert." Accordingly, for the same reasons discussed as to that element in Paragraph 128(d) *supra*, this element is literally present in the Accused Instrumentalities.

c. **(1b):** This element is substantially the same as element (1d) of claim 1 of the '611 patent. Accordingly, for the same reasons discussed as to that element in Paragraph 96(e) *supra*, this element is literally present in the Accused Instrumentalities.

d. **(1c):** This element is broader than element (1b) of claim 1 of the '270 patent. Accordingly, for the same reasons discussed as to that element in Paragraph 150(g) *supra*, this element is literally present in the Accused Instrumentalities.

e. **(1d):** This element is substantially the same as element (1c) of the '270 patent. Accordingly, for the same reasons discussed as to that element in Paragraph 150(h) *supra*, this element is literally present in the Accused Instrumentalities.

173. Because all elements of claim 1 of the '337 patent are literally present in the Accused Instrumentalities, Defendants directly infringe that claim when they make, sell, offer for sale, use, or import the Accused Instrumentalities in the United States.

174. As shown in Paragraphs 98-101 *supra*, Defendants directly infringed (and continue to directly infringe) at least claim 1 of the '337 patent by making, selling, offering for sale, importing, and/or using the Accused Instrumentalities in the United States during the life of the '337 patent. Accordingly, under 35 U.S.C. § 271(a), Defendants are liable to SG for their past, present, and ongoing direct infringement of the '337 patent.

COUNT 11: INDUCED INFRINGEMENT OF THE '337 PATENT

175. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-174 *supra* as if fully set forth herein.

176. Defendants have unlawfully induced infringement of at least one claim of the '337 patent by selling the Accused Instrumentalities to U.S. customers, and expressly instructing such customers on how to use the Accused Instrumentalities in an infringing manner, all while knowing of the '337 patent, and knowing (or being willfully blind) that using the Accused Instrumentalities infringes at least one claim of the '337 patent.

177. When Defendants' end-users—i.e., surgeons—actually use the side port cannula / helical blade or screw assembly to deliver PMMA bone cement to a patient's bone, they are "using" a system that satisfies all elements of at least claim 1 of the '337 patent. Such use constitutes direct infringement of at least claim 1 of the '337 patent.

178. Accordingly, Defendants' end-users—i.e., surgeons—directly infringe at least claim 1 of the '337 patent when they use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

179. As shown in Paragraphs 108-110 *supra*, Defendants provide extensive documentation and hands-on assistance to their end-customers, showing them how to use the Accused Instrumentalities in an infringing manner. Defendants' provision of such documentation and hands-on assistance constitutes inducing acts that induce end-users to commit direct infringement of at least claim 1 of the '337 patent.

180. As shown in Paragraphs 111-114 *supra*, Defendants were aware of the Patents-in-Suit, including the '337 patent, when they committed the inducing acts complained of above. As shown in Paragraphs 111-114 *supra*, Defendants were also aware—or else were willfully blind—

that its end-users' use of the Accused Instrumentalities directly infringes at least one claim of the Patents-in-Suit, including the '337 patent.

181. Therefore, for the foregoing reasons, Defendants are liable to SG for induced infringement of the '337 patent under 35 U.S.C. § 271(b).

COUNT 12: CONTRIBUTORY INFRINGEMENT OF THE '337 PATENT

182. SG repeats and realleges each and every allegation set forth in Paragraphs 1-181 *supra* as if fully set forth herein.

183. Defendants have unlawfully contributed to infringement of the '337 patent by making, selling, and distributing the Accused Instrumentalities in the United States, where the Accused Instrumentalities constitute a material part of the claimed invention, where Defendants knew the Accused Instrumentalities were especially adapted for use in infringement of the '337 patent, and where the Accused Instrumentalities are not staple articles or commodities of commerce suitable for substantial non-infringing use.

184. As shown in Paragraphs 172-173 *supra,* Defendants' end-users—i.e., surgeons—directly infringe at least claim 1 of the '337 patent when they use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

185. Since October 2017, Defendants have continually sold and offered to sell the Accused Instrumentalities to end-users in the United States. *See* Paragraphs 98-99 *supra*.

186. The Accused Instrumentalities sold by Defendants are components of the system claimed in at least claim 1 of the '337 patent, and constitute a material part of the claimed invention. Indeed, the Accused Instrumentalities include ***every*** part of the invention claimed in at least claim 1 of the '337 patent.

187. As shown in Paragraphs 51-73 *supra*, Defendants knew—or else were willfully

blind—that their end-users' ordinary use of the Accused Instrumentalities constitutes direct infringement of at least claim 1 of the '337 patent. Thus, Defendants knew that the Accused Instrumentalities were especially adapted for use in an infringement of the '337 patent.

188. The Accused Instrumentalities are not staple articles of commerce suitable for substantial non-infringing use. Rather, the ***only*** substantial use of the Accused Instrumentalities is to use them in the manner intended and directed by Defendants, which constitutes direct infringement of at least claim 1 of the '337 patent.

189. Accordingly, for the foregoing reasons, Defendants are liable to SG for contributory infringement of the '337 patent in violation of 35 U.S.C. § 271(c).

COUNT 13: DIRECT INFRINGEMENT OF THE '777 PATENT

190. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-189 *supra* as if fully set forth herein.

191. Defendants have directly infringed at least one claim of the '777 patent by making, selling, offering for sale, using, and/or importing the Accused Instrumentalities in the United States during the lifetime of the '777 patent.

192. For example, claim 11 of the '777 patent recites:

> (11pre). A method for long-term delivery of fluids to a bone of a patient, comprising:
>
> (11a) providing a bone screw having a cannulation, and having one or more threads disposed on a proximal end of the bone screw;
>
> (11b) providing an insert having one or more threads disposed on a proximal end of the insert configured to be coupled to the bone screw, wherein the one or more threads on the insert are configured to engage with the one or

more threads on the bone screw;

(11c) creating an aperture in skin of the patient;

(11d) inserting the bone screw into the bone of the patient through the aperture;

(11e) inserting a distal end of the insert through the cannulation in the bone screw and coupling the one or more threads on the proximal end of the insert to the one or more threads on the proximal end of the bone screw;

(11f) providing a fluid source;

(11g) coupling the fluid source to the insert;

(11h) and delivering a fluid from the fluid source to the insert;

(11i) wherein the insert at least partially protrudes through the skin when coupled to the bone screw.

193. The Accused Instrumentalities satisfy every element of this claim, either literally or under the doctrine of equivalents:

a. **(11pre)**: To the extent the preamble is limiting, which SG does not concede, the Accused Instrumentalities provide a "method" for delivering "fluids"—i.e., PMMA bone cement" (Ex. 7 at 5)—to bone. The bone cement is delivered on a "long-term" basis—i.e., it is intended to remain in the patient's bone either indefinitely, or at least until the implants are removed. Accordingly, all parts of this element are literally present in the Accused Instrumentalities.

b. **(11a):** The Accused Instrumentalities provide a bone screw—i.e., the helical blade or screw—which has a cannulation within it, and which has one or more threads at the proximal end of the cannula. *See* Ex. 7 at 31, 33, 40, 74. Thus, all

parts of this element are literally present in the Accused Instrumentalities.

c. **(11b):** The Accused Instrumentalities provide an insert—i.e., the side-opening cannula—which has one more threads on a proximal end, and which is configured to be coupled to (i.e., inserted into) the bone screw. *Id.* at 40. The threads of the side-opening cannula are configured to engage with the threads of the sleeve of the side-opening cannula, which is used to guide the side-opening cannula to the proper position within the bone screw cannulation. *Id.* Thus, this element is literally present in the Accused Instrumentalities. Or, if it is not literally present, it is present under the doctrine of equivalents, because the side-port cannula, sleeve, and bone-screw cannulation of the Accused Instrumentalities perform substantially the same function (guiding the insert to the proper location in the cannulation) in substantially the same way (threading) to achieve substantially the same result (proper insertion of the insert) as the claimed "one or more threads on the insert [that] are configured to engage with the one or more threads on the bone screw."

d. **(11c):** The Surgical Technique Guide instructs surgeons implanting the Accused Instrumentalities to create an aperture in the skin of the patient, to provide an opening for insertion of the bone screw and insert. *See id.* at 24. Thus, when surgeons perform the surgical procedure in accordance with Defendants' instructions, all parts of this element are literally met.

e. **(11d):** The Surgical Technique Guide instructs surgeons implanting the Accused Instrumentalities to insert the bone screw—i.e., the helical blade or screw—through the aperture in the patient's skin. *See id.* at 24-34. Thus, when

surgeons perform the surgical procedure in accordance with Defendants' instructions, all parts of this element are literally met.

f. **(11e):** The Surgical Technique Guide instructs surgeons implanting the Accused Instrumentalities to insert a distal end of the insert—i.e., the side-opening cannula—through the cannulation in the helical blade or screw. *See id.* at 47-49. It further instructs surgeons to couple the threads of the insert to the threads of the sleeve, and to insert the side-opening cannula through the threads on the proximal end of the bone screw. *Id.* at 40, 47-49. Thus, when surgeons perform the surgical procedure in accordance with Defendants' instructions, all parts of this element are literally met. Or, if not literally met, it is met under the doctrine of equivalents, because the side-port cannula, sleeve, and bone-screw cannulation of the Accused Instrumentalities perform substantially the same function (guiding the insert to the proper location in the cannulation) in substantially the same way (threading) to achieve substantially the same result (proper insertion of the insert) as the claimed step of "coupling the one or more threads on the proximal end of the insert to the one or more threads on the proximal end of the bone screw."

g. **(11f):** The Accused Instrumentalities provide a fluid source—i.e., cement injection syringes. *See id.* at 43-45. Thus, all parts of this element are literally present in the Accused Instrumentalities.

h. **(11g):** The Surgical Technique Guide instructs surgeons to couple the cement injection syringes to the side-opening cannula. *See id.* at 46-49. Thus, when surgeons perform the surgical procedure in accordance with Defendants'

instructions, all parts of this element are literally met.

i. **(11h):** The Surgical Technique Guide instructs surgeons to deliver bone cement from the cement injection syringes to the side-opening cannula. *Id.* Thus, when surgeons perform the surgical procedure in accordance with Defendants' instructions, all parts of this element are literally met.

j. **(11i):** As shown in the Surgical Technique Guide, the side-opening cannula at least partially protrudes through the skin of the patient when it is coupled to the helical blade or screw. *Id.* at 47-50. Thus, when surgeons perform the surgical procedure in accordance with Defendants' instructions, all parts of this element are literally met.

194. Because all elements of claim 11 of the '777 patent are literally or equivalently present in the Accused Instrumentalities (including the surgical technique involving the Accused Instrumentalities set forth in the Guide), Defendants directly infringe that claim when they make, sell, offer for sale, use, or import the Accused Instrumentalities in the United States.

195. As shown in Paragraphs 98-101 *supra*, Defendants directly infringed (and continue to directly infringe) at least claim 11 of the '777 patent by making, selling, offering for sale, importing, and/or using the Accused Instrumentalities in the United States during the life of the '777 patent. Accordingly, under 35 U.S.C. § 271(a), Defendants are liable to SG for their past, present, and ongoing direct infringement of the '777 patent.

COUNT 14: INDUCED INFRINGEMENT OF THE '777 PATENT

196. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-195 *supra* as if fully set forth herein.

197. Defendants have unlawfully induced infringement of at least one claim of the '777

patent by selling the Accused Instrumentalities to U.S. customers, and expressly instructing such customers on how to use the Accused Instrumentalities in an infringing manner, all while knowing of the '777 patent, and knowing (or being willfully blind) that using the Accused Instrumentalities infringes at least one claim of the '777 patent.

198. When Defendants' end-users—i.e., surgeons—actually use the side port cannula / helical blade or screw assembly to deliver PMMA bone cement to a patient's bone, they are performing a "method" that satisfies all elements of at least claim 11 of the '777 patent. Such performance of the method constitutes direct infringement of at least claim 11 of the '777 patent.

199. Accordingly, Defendants' end-users—i.e., surgeons—directly infringe at least claim 11 of the '777 patent when they use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

200. As shown in Paragraphs 108-110 *supra*, Defendants provide extensive documentation and hands-on assistance to their end-customers, showing them how to use the Accused Instrumentalities in an infringing manner. Defendants' provision of such documentation and hands-on assistance constitutes inducing acts that induce end-users to commit direct infringement of at least claim 11 of the '777 patent.

201. As shown in Paragraphs 111-114 *supra*, Defendants were aware of the Patents-in-Suit, including the '777 patent, when they committed the inducing acts complained of above. As shown in Paragraphs 111-114 *supra*, Defendants were also aware—or else were willfully blind—that its end-users' use of the Accused Instrumentalities directly infringes at least one claim of the Patents-in-Suit, including the '777 patent.

202. Therefore, for the foregoing reasons, Defendants are liable to SG for induced infringement of the '777 patent under 35 U.S.C. § 271(b).

COUNT 15: CONTRIBUTORY INFRINGEMENT OF THE '777 PATENT

203. SG repeats and realleges each and every allegation set forth in Paragraphs 1-202 *supra* as if fully set forth herein.

204. Defendants have unlawfully contributed to infringement of the '777 patent by making, selling, and distributing the Accused Instrumentalities in the United States, where the Accused Instrumentalities constitute a material part of the claimed invention, where Defendants knew the Accused Instrumentalities were especially adapted for use in infringement of the '777 patent, and where the Accused Instrumentalities are not staple articles or commodities of commerce suitable for substantial non-infringing use.

205. As shown in Paragraphs 193-194 *supra,* Defendants' end-users—i.e., surgeons—directly infringe at least claim 11 of the '777 patent when they use the Accused Instrumentalities in the manner specifically intended and directed by Defendants.

206. Since October 2017, Defendants have continually sold and offered to sell the Accused Instrumentalities to end-users in the United States. *See* Paragraphs 98-99 *supra*.

207. The Accused Instrumentalities sold by Defendants are components of the system claimed in at least claim 11 of the '777 patent, and constitute a material part of the claimed invention. Indeed, the Accused Instrumentalities include ***every*** component needed to practice the method invention claimed in at least claim 11 of the '777 patent.

208. As shown in Paragraphs 51-73 *supra*, Defendants knew—or else were willfully blind—that their end-users' ordinary use of the Accused Instrumentalities constitutes direct infringement of at least claim 11 of the '777 patent. Thus, Defendants knew that the Accused Instrumentalities were especially adapted for use in an infringement of the '777 patent.

209. The Accused Instrumentalities are not staple articles of commerce suitable for

substantial non-infringing use. Rather, the ***only*** substantial use of the Accused Instrumentalities is to use them in the manner intended and directed by Defendants, which constitutes direct infringement of at least claim 11 of the '777 patent.

210. Accordingly, for the foregoing reasons, Defendants are liable to SG for contributory infringement of the '777 patent in violation of 35 U.S.C. § 271(c).

REMEDIES, EXCEPTIONAL CASE, ENHANCED DAMAGES

211. SG repeats and re-alleges each and every allegation set forth in Paragraphs 1-210 *supra* as if fully set forth herein.

212. Defendants' direct infringement (Counts 1, 4, 7, 10, 13), induced infringement (Counts 2, 5, 8, 11, 14), and contributory infringement (Counts 3, 6, 9, 12, 15) has caused significant damage to SG. As a result, SG is entitled to an award of damages adequate to compensate it for the infringement, but in no event less than a reasonable royalty pursuant to 35 U.S.C. § 284. SG is also entitled to recover prejudgment interest, post-judgment interest, and costs.

213. As shown in Paragraphs 51-73 *supra*, years before Defendants introduced the Accused Instrumentalities in the United States, they knew of the Patents-in-Suit, and knew (or were willfully blind) that making, selling, offering for sale, using, and/or importing the Accused Instrumentalities in the United States infringes those patents. Despite having such knowledge (or willful blindness), Defendants elected to introduce the Accused Instrumentalities in the United States in October 2017, and have committed continual direct infringement since that time, by making, selling, offering for sale, using, and/or importing the Accused Instrumentalities in the United States. Defendants have also continually committed indirect infringement since October 2017, by inducing its end-users (i.e., surgeons) to make and use the Accused Instrumentalities in an infringing manner, and by contributing to its end-users' infringing use of the Accused

Instrumentalities (which have no substantial non-infringing uses).

214. Because Defendants have continually committed direct and indirect infringement over a period of nearly five years, despite knowing (or being willfully blind) of their infringement throughout that period, Defendants' infringement has been willful.

215. Defendants' infringing conduct has also been egregious. Despite knowing of (or being willfully blind to) their infringement, Defendants committed infringement over a period of nearly five years, and they continue to infringe today. J&J, Defendants' parent company, is the world's largest healthcare company, with over $90 billion in annual revenue.[2] Meanwhile, SG is a small company, owned by an individual inventor. On information and belief, Defendants persisted in their willful infringement, at least in part, because they believed they could use their superior financial resources to overwhelm SG in litigation. If proven, this would constitute "egregious" conduct, warranting an award of enhanced damages.

216. Defendants' dealings with Dr. Sweeney and Flow-FX were also egregious. In 2014-2015, Dr. Sweeney approached Defendants in good faith, seeking to partner with them in the manufacture, marketing, and distribution of the patented invention. Defendants welcomed Dr. Sweeney's advances, setting up a meeting between him and multiple high-level executives of Defendants. At that meeting, and in other communications, Dr. Sweeney touted the advantages of the patented Flow-Nail—including that it "[e]nables the delivery of injectable bone void fillers via the Side Port Cannula (Ex. 22 at 11)—and repeatedly stressed that it was protected by his "IP," i.e., the Patents-in-Suit. *Id.* at 19; Ex. 26 at 1. Defendants declined to partner with Dr. Sweeney, but they also gave no indication that they intended to introduce an infringing, competing product in the United States. Instead, Defendants waited two years, then introduced the infringing TFNA

[2] https://www.cnbc.com/2022/01/25/covid-and-jnj-earnings-q4-2021.html

product—which is virtually indistinguishable from the Flow Nail product that Dr. Sweeney had presented to them. Defendants even took Dr. Sweeney's terminology, renaming what they had called the "injection cannula" in the PFNA product (Ex. 27 at 45) the "side-opening cannula" (Ex. 7 at 46), in direct emulation of Dr. Sweeney's "Side Port Cannula." Ex. 22 at 11.

217. For at least the foregoing reasons, Defendants' conduct has been willful and egregious. Accordingly, under 35 U.S.C. § 284, the Court should enhance SG's damages in this case by up to three times the amount found or assessed.

218. For at least the foregoing reasons, this case is an "exceptional" case within the meaning of 35 U.S.C. § 285. Accordingly, SG is entitled to an award of attorneys' fees and costs, and the Court should award such fees and costs.

219. The Court should also enter a permanent injunction, permanently enjoining Defendants from infringing the Patents-in-Suit, because Defendants' ongoing infringement is causing irreparable harm to SG.

JURY DEMAND

220. SG demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, SG prays for relief as follows:

1. That judgment be entered in favor of SG, and against Defendants;

2. That SG be awarded damages adequate to compensate it for Defendants' infringement of the Patents-in-Suit, in an amount to be determined at trial, as well as pre-judgment and post-judgment interest thereon;

3. That SG be awarded the costs of suit;

4. That Defendants' infringement be declared willful and egregious;

5. That the Court increase SG's damages up to three times the amount assessed under

35 U.S.C. § 284;

6. That the Court declare this an exceptional case under 35 U.S.C. § 285, and award SG its attorneys' fees and costs incurred in this action;

7. That the Court grant a permanent injunction preventing Defendants from continuing to infringe the patents-in-suit; and,

8. That the Court grant such further relief as it deems just and proper.

Dated: October 17, 2022

Respectfully submitted,

Stamoulis & Weinblatt, LLC

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* Admission *pro hac vice* anticipated