UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

BONUTTI SKELETAL INNOVATIONS LLC,

Plaintiff,

vs.

BIOMET, INC., BIOMET SPORTS MEDICINE, LLC, and BIOMET MANUFACTURING CORPORATION,

Defendants.

Civil Action No. 2:13-CV-00377

JURY TRIAL DEMANDED

AMENDED COMPLAINT

1. Plaintiff, Bonutti Skeletal Innovations LLC ("Bonutti Skeletal" or "Plaintiff") hereby asserts claims for breach of contract and patent infringement against Biomet, Inc. ("Biomet"), Biomet Sports Medicine, LLC ("BSM"), and Biomet Manufacturing Corporation ("BMC") (collectively, "Defendants"), and alleges as follows:

THE PARTIES

2. Bonutti Skeletal is a Delaware limited liability company having a place of business at 2400 Dallas Parkway, Suite 200, Plano, TX 75093. Bonutti Skeletal is a wholly owned subsidiary of Acacia Research Group LLC ("ARG"). ARG is a Texas limited liability company having a place of business at 2400 Dallas Parkway, Suite 200, Plano, TX 75093.

- 3. Biomet is an Indiana corporation having a primary place of business at 56 East Bell Drive, Warsaw, Indiana 46581-0587.
- 4. BSM is an Indiana limited liability corporation having a primary place of business at 56 East Bell Drive, Warsaw, Indiana 46581-0587. BSM was formerly known as Arthrotek, Inc. until it changed its corporate name to BSM in January 2007.
- 5. BSM is a wholly owned subsidiary of Biomet. Biomet directs and/or controls the activities of BSM.
- 6. BMC is an Indiana corporation having a primary place of business at 56 East Bell Drive, Warsaw, Indiana 46581-0587.
- 7. BMC is a wholly owned subsidiary of Biomet. Biomet directs and/or controls the activities of BMC.

JURISDICTION AND VENUE

- 8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 because this action arises under the patent laws of the United States, including 35 U.S.C. § 271 et seq. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy, without interest and costs, exceeds \$75,000 and is between citizens of different states.
- 9. This Court has personal jurisdiction over Defendants because Defendants have engaged in substantial and not isolated activity within this District.

- 10. Defendants offer to sell, sell and distribute their suture anchor, knee systems, hip implants, bone spacers and wedges and/or tissue harvesting products, and/or related instruments and products, that either infringe at least one of the patents asserted in this Complaint or are for use in infringing procedures, to healthcare institutions and/or medical professionals within this District. Defendants' suture anchor, knee systems, hip implants, bone spacers and wedges and/or tissue harvesting products and/or related instruments and products are used, including in infringing procedures, by healthcare institutions and/or medical professionals within this District. Defendants, independently and/or collectively, have committed, contributed to and/or induced acts of patent infringement within this District.
 - 11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

- 12. U.S. Patent No. 5,921,986 ("the '986 patent"), entitled "Bone Suture," was lawfully issued on July 13, 1999 to the inventor Peter M. Bonutti ("Dr. Bonutti"). Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '986 patent including the rights to enforce and collect damages for all past, present and future infringements of the '986 patent and the use thereof. A copy of the '986 patent is attached as **Exhibit A**.
- 13. U.S. Patent No. 6,099,531 ("the '531 patent"), entitled "Changing Relationship Between Bones," was lawfully issued on August 8, 2000 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '531 patent including the rights to enforce and collect damages for all past, present and future

infringements of the '531 patent and the use thereof. A copy of the '531 patent is attached as **Exhibit B**.

- 14. U.S. Patent No. 6,423,063 ("the '063 patent"), entitled "Changing Relationship Between Bones," was lawfully issued on July 23, 2002 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '063 patent including the rights to enforce and collect damages for all past, present and future infringements of the '063 patent and the use thereof. A copy of the '063 patent is attached as **Exhibit C**.
- 15. U.S. Patent No. 6,638,279 ("the '279 patent"), entitled "Method of Positioning Body Tissue Relative to a Bone," was lawfully issued on October 28, 2003 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '279 patent including the rights to enforce and collect damages for all past, present and future infringements of the '279 patent and the use thereof. A copy of the '279 patent is attached as **Exhibit D**.
- 16. U.S. Patent No. 6,702,821 ("the '821 patent"), entitled "Instrumentation for Minimally Invasive Joint Replacement and Methods for Using the Same," was lawfully issued on March 9, 2004 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '821 patent including the rights to enforce and collect damages for all past, present and future infringements of the '821 patent and the use thereof. A copy of the '821 patent is attached as **Exhibit E**.
- 17. U.S. Patent No. 7,070,557 ("the '557 patent"), entitled "Tissue Graft Material and Method of Making," was lawfully issued on March 9, 2004 to the inventor Dr. Bonutti.

Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '557 patent including the rights to enforce and collect damages for all past, present and future infringements of the '557 patent and the use thereof. A copy of the '557 patent is attached as **Exhibit F**.

- 18. U.S. Patent No. 7,087,073 ("the '073 patent"), entitled "Method of Securing Body Tissue," was lawfully issued on August 8, 2006 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '073 patent including the rights to enforce and collect damages for all past, present and future infringements of the '073 patent and the use thereof. A copy of the '073 patent is attached as **Exhibit G**.
- 19. U.S. Patent No. 7,104,996 ("the '996 patent"), entitled "Method of Performing Surgery," was lawfully issued on September 12, 2006 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '996 patent including the rights to enforce and collect damages for all past, present and future infringements of the '996 patent and the use thereof. A copy of the '996 patent is attached as **Exhibit H**.
- 20. U.S. Patent No. 7,708,740 ("the '740 patent"), entitled "Method for Total Knee Arthroplasty and Resecting Bone in Situ," was lawfully issued on May 4, 2010 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '740 patent including the rights to enforce and collect damages for all past, present and future infringements of the '740 patent and the use thereof. A copy of the '740 patent is attached as **Exhibit I**.

- 21. U.S. Patent No. 7,806,896 ("the '896 patent"), entitled "Knee Arthroplasty Method," was lawfully issued on October 5, 2010 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '896 patent including the rights to enforce and collect damages for all past, present and future infringements of the '896 patent and the use thereof. A copy of the '896 patent is attached as **Exhibit J**.
- 22. U.S. Patent No. 7,806,897 ("the '897 patent"), entitled "Knee Arthroplasty and Preservation of the Quadriceps Mechanism," was lawfully issued on October 5, 2010 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '897 patent including the rights to enforce and collect damages for all past, present and future infringements of the '897 patent and the use thereof. A copy of the '897 patent is attached as **Exhibit K**.
- 23. U.S. Patent No. 7,828,852 ("the '852 patent"), entitled "Inlaid Articular Implant," was lawfully issued on November 9, 2010 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '852 patent including the rights to enforce and collect damages for all past, present and future infringements of the '852 patent and the use thereof. A copy of the '852 patent is attached as **Exhibit L**.
- 24. U.S. Patent No. 7,931,690 ("the '690 patent"), entitled "Method of Resurfacing an Articular Surface of a Bone," was lawfully issued on April 26, 2011 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '690 patent including the rights to enforce and collect damages for all past, present and future infringements of the '690 patent and the use thereof. A copy of the '690 patent is attached as **Exhibit M**.

- 25. U.S. Patent No. 8,133,229 ("the '229 patent"), entitled "Knee Arthroplasty Method," was lawfully issued on March 13, 2012 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '229 patent including the rights to enforce and collect damages for all past, present and future infringements of the '229 patent and the use thereof. A copy of the '229 patent is attached as **Exhibit N**.
- 26. U.S. Patent No. 8,147,514 ("the '514 patent"), entitled "Apparatus and Method for Securing a Portion of a Body," was lawfully issued on April 3, 2012 to the inventor Dr. Bonutti. Bonutti Skeletal is the owner, through assignment, of the entire right, title and interest in and to the '514 patent including the rights to enforce and collect damages for all past, present and future infringements of the '514 patent and the use thereof. A copy of the '514 patent is attached as **Exhibit O**.

THE BACKGROUND

- 27. Dr. Bonutti is an orthopedic surgeon that has performed over 20,000 orthopedic surgical procedures.
- 28. Because of Dr. Bonutti's expertise, insight, experience and research efforts, Dr. Bonutti is an inventor or co-inventor of over 150 U.S. patents, including the '986 patent, the '531 patent, the '063 patent, the '279 patent, the '821 patent, the '557 patent, the '073 patent, the '996 patent, the '740 patent, the '896 patent, the '897 patent, the '852 patent, the '690 patent, the '229 patent, and the '514 patent (collectively, the "patents-in-suit").
- 29. The patents-in-suit involve specialized procedures, instruments, systems, kits and apparatuses invented by Dr. Bonutti relating to suture anchors, knee systems, hip implants, bone spacers and wedges, tissue harvesting and graft material, and related instruments used in certain

surgical procedures, including, for example, bone and joint fixation and body-tissue reattachment.

- 30. Defendants design, manufacture, and market products used primarily by musculoskeletal medical specialists and health care professionals in both surgical and non-surgical therapy. Defendants' products include reconstructive products, including orthopedic joint replacement devices, bone cements and accessories, autologous therapies and dental reconstructive implants; arthroscopy products, including suture anchors; fixation products, including electrical bone growth stimulators, internal and external orthopedic fixation devices, craniomaxillofacial implants and bone substitute materials; spinal products, including spinal stimulation devices, spinal hardware and orthobiologics; and other products, such as soft goods and bracing products.
- 31. On January 10, 2000, Dr. Bonutti met with Joel Pratt, President of BSM, to discuss Dr. Bonutti's work. Specifically, BSM was interested in licensing Dr. Bonutti's Multi-Tak Suture Anchor line, and manufacturing and selling a version of the Multi-Tak Suture Anchor with BSM's LactoSorb Polymer. BSM was also interested in discussing Dr. Bonutti's patents covering other technologies. In addition to the President of BSM, the meeting was attended by: Tony Fleming, Vice President of Research and Development; Larry Foster, Area Vice President; Joel Higgins, Project Manager; Dave Nolan, Director of Marketing; Tim Weis, Biomet Distributor State of Illinois; and Dan Merrill, Associate for Tim Weis.
- 32. In the years following the 2000 meeting, Dr. Bonutti and representatives of Biomet would meet and discuss the suture anchor market. Representatives of Biomet would visit the booth of MarcTec, LLC ("MarcTec"), Dr. Bonutti's suture anchor company, at the American

Association of Orthopedic Surgeons (AAOS) annual convention, where they would examine MarcTec's products, including the Multi-Tak Suture Anchor, and take product literature promoting MarcTec's products. The product literature provided by MarcTec identified patents covering MarcTec's technology. These meetings and interactions occurred for a number of years and several non-disclosure agreements were entered into between Biomet, and its subsidiaries, and Dr. Bonutti's companies over the years.

- 33. On December 13, 2005, Dr. Bonutti met with Kevin Stone, the Vice President of Operations for BSM to discuss Dr. Bonutti's Meniscal Fixation and Knotless Suture Anchors. Prior to that meeting, a list of Dr. Bonutti's patents covering suture anchors was provided to Dave Ahlersmeyer, Vice President of Intellectual Property and Associate General Counsel of Biomet. The list of Dr. Bonutti's patents included the '279 patent, one of the patents-in-suit.
- 34. By December 2006, BSM entered into a License Agreement with Dr. Bonutti's company, MarcTec (the "MarcTec License Agreement"), that granted BSM a license to 45 patents, including the '073 patent, one (1) of the patents-in-suit, and reissues, divisions, and continuations thereof, in exchange for an upfront license fee, minimum payments and royalty payments. The licensed patents covered suture anchors and fasteners, multiple anchor assemblies, and insertion instrumentation.
- 35. At least as of December 2006, Defendants were aware of and had constructive notice of the '986 patent, the '531 patent, the '063 patent, the '279 patent, the '821 patent, the '557 patent, the '073 patent, and the '996 patent. The other patents-in-suit had not yet issued by December 2006. The MarcTec License Agreement licensed continuation and divisional patent applications and Biomet and BSM continued to monitor the patents from Dr. Bonutti.

- 36. From November 2010 through March 2011, Mr. Stone from BSM contacted Dr. Bonutti about licensing the '896 patent. At that time, Dr. Bonutti informed Mr. Stone that he was not able to license the '896 patent.
- 37. In March 2012, Defendants sought to purchase some of Dr. Bonutti's patents relating to suture anchors, fasteners and minimally invasive surgery.
- 38. From December 2006 when BSM entered the License Agreement with MarcTec, until June 2012, multiple people from Defendants for a period of multiple years requested broader access to Dr. Bonutti's patent portfolio.
- 39. On or about June 8, 2012, ARG acquired from several of Dr. Bonutti's companies an extensive array of patents (hereinafter the "Bonutti Patent Portfolio") which included the patents-in-suit. The rights of MarcTec under the MarcTec Licensing Agreement were also acquired by ARG. In August 2012, the patents-in-suit and other patents, as well as the rights of MarcTec under the MarcTec Licensing Agreement were assigned to Bonutti Skeletal.
- 40. Because Biomet, and particularly BMC through corporate name change, had previously licensed patents from Dr. Bonutti, and because Defendants had previously expressed an interest in licensing additional Bonutti patents, in June 2012, Defendants began discussing licensing of the Bonutti Patent Portfolio, including the patents-in-suit. As part of those discussions, on August 13, 2012, BMC on behalf of Biomet and ARG as an agent of and on behalf of Bonutti Skeletal entered a Mutual Non-Disclosure Agreement (the "NDA") to explore business licensing opportunities relating to the Bonutti Patent Portfolio, including the patents-insuit.

- 41. Pursuant to the NDA, the parties agreed "not to use or disclose any Confidential Information provided to it by or obtained by it from the other party for any reason including its own use or for any purpose except to carry out discussions concerning, and the undertaking of" the potential licensing relationship. Without disclosing the specifics of these discussions, which are subject to the NDA, but which Defendant Biomet has to some extent already disclosed in an action Biomet filed in the Northern District of Indiana, these discussions and associated documents involved licensing the Bonutti Patent Portfolio.
- 42. In August 2012, Robert Rauker, then Vice President of ARG, and acting as agent of Bonutti Skeletal, had a telephone conference with Biomet during which they discussed Defendants' interest in the Bonutti Patent Portfolio. As a result of this conversation, Defendants had actual and/or constructive notice of the patents-in-suit at the latest by the end of August 2012.
- 43. Mr. Rauker also advised Defendants that the 2006 MarcTec License Agreement had been assigned to Bonutti Skeletal and that future royalty payments should be sent to Bonutti Skeletal. Since September 26, 2012, Biomet has been making royalty payments to Bonutti Skeletal on some but not all of the products covered under the MarcTec License Agreement.
- 44. In September 2012, Mr. Rauker advised Defendants that Bonutti Skeletal had filed multiple patent infringement suits against several orthopedic companies involving at least some of the patents-in-suit. Mr. Rauker advised Defendants that they were in the process of obtaining the ability to license the patents that Defendants had expressed an interest in previously.

- 45. In January 2013, Biomet and Bonutti Skeletal had a series of discussions, during which the pending Bonutti Skeletal litigations were discussed as well as the business licensing opportunity. At that time, Defendants requested a list of the pending Bonutti Skeletal litigations, and the patents asserted in each litigation.
- 46. On January 27, 2013, at the Defendants' request, Mr. Rauker provided Defendants with a list of patents available for licensing; and a patent chart identifying Bonutti Skeletal's patents, specific claim numbers, and related Biomet products all of which were the subject of the licensing negotiations. The next day Defendants inquired when they would receive a licensing proposal from Bonutti Skeletal.
- 47. On February 1, 2013, Mr. Rauker provided Defendants with Bonutti Skeletal's proposed licensing terms for the patents-in-suit, among other patents.
- 48. On or about February 7, 2013, as per Defendants' earlier request, Mr. Rauker provided Defendants with a list of the litigations that Bonutti Skeletal had filed in September of 2012, and the asserted patents in each of those litigations. Mr. Rauker also requested feedback on Plaintiffs' proposal but was met with delay and further requests for information by Defendants.
- 49. On February 20, 2013, Mr. Rauker had a telephone conference with Defendants during which they discussed the terms of the licensing proposal, Defendants' failure to pay royalties under the License Agreement, and the status of the pending Bonutti Skeletal litigations.

- 50. On February 27, 2013, Bonutti Skeletal discussed the licensing proposal with Defendants and the desire to get a deal in place, but Bonutti Skeletal was met with further delay and additional requests for information.
- 51. On March 1, 2013, Mr. Rauker provided Defendants with an updated list of patents subject to Plaintiffs' licensing proposal and other information requested by Defendants. The updated list added newly issued patents and new patent applications. Mr. Rauker requested that Defendants accept the proposal or provide a counter-proposal by Friday, March 8, 2013.
- 52. On March 8, 2013, in a complete reversal of prior actions and communications, and after delaying a response to Bonutti Skeletal's licensing proposed all while obtaining valuable information from Bonutti Skeletal, Defendants advised Mr. Rauker that Defendants concluded that they do not need a license and, as a result, they would not be accepting or making a counter-proposal. Less than two hours later, Biomet filed a declaratory judgment in the District of Indiana seeking a judgment that Biomet did not infringe any one of the patents-in-suit and that every one of the patents-in-suit were invalid.
- 53. On March 11, 2013, still unaware that Biomet had filed suit against Bonutti Skeletal, which was served on March 14, 2013, Mr. Rauker thanked Defendants for their response and requested a meeting the following week to speak with them about Defendants' position.
- 54. Defendants had actual and/or constructive notice and knowledge of each of the patents-in-suit at the latest in August 2012.

COUNT ONE (1): INFRINGEMENT OF THE '986 PATENT

- 55. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 56. Defendants have and had actual and/or constructive knowledge of the '986 patent.
- 57. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '986 patent, directly, indirectly, literally and/or equivalently.
- 58. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System with ZipLoopTM Technology. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System in a manner that practices at least the method of claim 64 of the '986 patent. Defendants, among other things, have created and distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled ACL Reconstruction, Femoral Fixation for ACL Reconstruction, and Ankle Syndesmosis, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the EzLocTM

Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System in a manner that practices the method of at least claim 64 of the '986 patent. By these actions, the Defendants, with actual and/or constructive knowledge of the '986 patent, have infringed and continue to infringe at least claim 64 of the '986 patent, literally or equivalently.

- 59. Defendants have contributed to and continue to contribute to the infringement of the '986 patent by selling, offering to sell, distributing, supplying, and/or importing Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System and related instruments and products, that are for use in a method that practices at least claim 64 of the '986 patent. Defendants further contributed to and continue to contribute to the infringement of the '986 patent by creating and/or distributing Biomet surgical technique guides, including, but not limited to, surgical technique guides entitled ACL Reconstruction, Femoral Fixation for ACL Reconstruction, and Ankle Syndesmosis, that promote, teach, instruct, disclose, set forth, demonstrate, encourage, and/or contribute to the implantation of the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System in a manner that practices the method of at least claim 64 of the '986 patent.
- 60. These Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation -15-

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Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or suture anchor related instruments and products are not staple articles or commodities of commerce suitable for substantial noninfringing use as, such suture anchors, and related instruments and products are designed to be used only in a manner that infringes at least claim 64 of the '986 patent, and all the instructions for use and surgical technique guides supplied by Biomet only teach one way to use such products and/or related instruments and products, and those techniques infringe at least claim 64 of the '986 patent.

- 61. Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM, and the ZipTightTM Fixation System, and/or related instruments and products, are a material part of the method of the '986 patent for at least the reason that such suture anchors, and/or related instruments and products, are specially designed for use in and are used to practice the method of at least claim 64 the '986 patent.
- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals in implanting such Biomet suture anchors, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the ACL Reconstruction, the

Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, that encourage, promote, instruct, teach, and induce implantation of such Biomet suture anchors with such instruments in a manner that practices the method of at least claim 64 of the '986 patent.

- 63. With knowledge of the '986 patent and the specific intent to encourage, promote, instruct, teach, contribute to, and induce the infringement of the '986 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or related Biomet instruments and products, in a manner that practices the method of at least claim 64 of the '986 patent, by: (1) creating, distributing, and supplying surgical technique guides and instructions for use, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, that encourage, promote, instruct, teach, contribute to and induce the use of such Biomet suture anchors and/or related instruments and products in a manner that practices the method of at least claim 64 of the '986 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of suture anchor related instruments and products for use with such Biomet suture anchors that are specially designed for use in and are used in a manner that practices the method of at least claim 64 of the '986 patent.
- 64. Medical professionals have infringed and continue to infringe the '986 patent, directly, indirectly, literally and by equivalents, by using Biomet suture anchors, including, but

not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or related instruments and products during surgeries in the United States in a manner that practices the method of at least claim 64 of the '986 patent.

65. Defendants had and have actual and/or constructive knowledge of the infringement of the '986 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '986 patent, Defendants did create and/or distribute, and have created and distributed instructions for use and surgical technique guides, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, for Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or suture anchor related instruments and products, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet suture anchors and/or related instruments and products in a manner that practices the method of at least claim 64 of the '986 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet suture anchors and/or related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claim 64 of the '986 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '986 patent as a result of the medical professionals use of Biomet suture anchors and related instruments, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claim 64 of the '986 patent.
- 67. Defendants' infringement of the '986 patent is and has been willful and deliberate.
- 68. Defendants knew of the '986 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT TWO (2): INFRINGEMENT OF THE '279 PATENT

- 69. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 70. Defendants have and had actual and/or constructive knowledge of the '279 patent.

- 71. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '279 patent, directly, indirectly, literally and/or equivalently.
- 72. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System in a manner that practices at least the method of claim 6 of the '279 patent. Defendants, among other things, have created and distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled ACL Reconstruction, Femoral Fixation for ACL Reconstruction, and Ankle Syndesmosis, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System in a manner that practices at least the method of claim 6 of the '279 patent. By these actions, the Defendants with actual and/or constructive knowledge of the '279 patent, have infringed and continue to infringe at least claim 6 of the '279 patent, literally or equivalently.

- 73. Defendants have contributed to, and continue to contribute to the infringement of the '279 patent by selling, offering to sell, supplying, and/or importing Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and related instruments and products, that are for use in a method that practices at least claim 6 of the '279 patent. Defendants further contributed to and continue to contribute to the infringement of the '279 patent by creating and/or distributing Biomet surgical technique guides, including, but not limited to, surgical technique guides entitled ACL Reconstruction Femoral Fixation for ACL Reconstruction, and Ankle Syndesmosis, that promote, teach, instruct, disclose, set forth, demonstrate, encourage, and/or contribute to the implantation of the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM
- 74. These Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or suture anchor related instruments and products are not staple articles or commodities of commerce suitable for substantial noninfringing use as, such suture anchors and related instruments and products are designed to be used only in a manner that infringes at least claim 6 of the '279 patent, and all the instructions for use and surgical technique guides supplied by Biomet only teach one way to use such products and/or related instruments and products, and those techniques infringe at least claim 6 of the '279 patent.

- 75. Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or related instruments and products, are a material part of the method of the '279 patent for at least the reason that such suture anchors, and/or related instruments and products, are specially designed for use in and are used to practice the method of at least claim 6 the '279 patent.
- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products, for use by medical professionals in implanting such Biomet suture anchors, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, that encourage, promote, instruct, teach, and induce implantation of such Biomet suture anchors with such instruments in a manner that practices the method of at least claim 6 of the '279 patent.
- 77. With knowledge of the '279 patent and the specific intent to encourage, promote, instruct, teach, contribute to, and induce the infringement of the '279 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within

the United States Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or related Biomet instruments and products, in a manner that practices the method of at least claim 6 of the '279 patent, by: (1) creating, distributing, and supplying surgical technique guides and instructions for use, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, that encourage, promote, instruct, teach, contribute to and induce the use of such Biomet suture anchors and/or related instruments and products, that encourage, promote, instruct, teach, contribute to, and induce the use of such Biomet suture anchors and/or related instruments and products in a manner that practices the method of at least claim 6 of the '279 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of suture anchor related instruments and products for use with such Biomet suture anchors that are specially designed for use in and are used in a manner that practices the method of at least claim 6 of the '279 patent.

78. Medical professionals have infringed and continue to infringe the '279 patent, directly, indirectly, literally and by equivalents, by using Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, and/or related instruments and products during surgeries in the United States in a manner that practices the method of at least claim 6 of the '279 patent.

- 79. Defendants had and have actual and/or constructive knowledge of the infringement of the '279 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '279 patent, Defendants did create and/or distribute, and have created and distributed instructions for use and surgical technique guides, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis, for Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLoc[™] Femoral Fixation Device with ZipLoop[™] Technology, and the ZipTight[™] Fixation System, and/or suture anchor related instruments and products, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet suture anchors and/or related instruments and products in a manner that that practices the method of at least claim 6 of the '279 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet suture anchors and/or related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claim 6 of the '279 patent.
- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '279 patent as a result of the medical professionals use of Biomet suture anchors and related instruments, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Technology, and the ZipTightTM Fixation System, in a manner that follows the methods and techniques set forth in Biomet's

instructions for use and surgical technique guides for such products, such as the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claim 6 of the '279 patent.

- 81. Defendants' infringement of the '279 patent is and has been willful and deliberate.
- 82. Defendants knew of the '279 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT THREE (3): INFRINGEMENT OF THE '514 PATENT

- 83. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 84. Defendants have and had actual and/or constructive knowledge of the '514 patent.
- 85. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '514 patent, directly, indirectly, literally and/or equivalently.
- 86. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and

the ZipTightTM Fixation System that embody the elements of at least claim 1 of the '514 patent. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System. Defendants, among other things, have created and distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled the ACL Reconstruction, Femoral Fixation for ACL Reconstruction, and Ankle Syndesmosis, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation and use of the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, which products embody the elements of at least claim 1 of the '514 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '514 patent, have infringed and continue to infringe at least claim 1 of the '514 patent, literally or equivalently.

87. Defendants have contributed to and continue to contribute to the infringement of the '514 patent by making, selling, offering to sell, supplying, and/or importing Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System that embody the elements of at least claim 1 of the '514 patent. Defendants further contribute to and have contributed to the infringement of the '514 patent by making, selling, offering to sell,

distributing, supplying and/or importing related instruments and products for use by medical professionals to implant and use such Biomet suture anchors and by creating and/or distributing Biomet surgical technique guides, including, but not limited to, the surgical technical guides entitled the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, that promote, teach, instruct, disclose, set forth, demonstrate, encourage, and/or contribute to the implantation and use of such Biomet suture anchors that embody the elements of at least claim 1 of the '514 patent.

- 88. These Biomet suture anchors, including, but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, are not staple articles or commodities of commerce suitable for substantial noninfringing use as such Biomet suture anchors embody the elements of at least claim 1 of the '514 patent.
- 89. Biomet suture anchors, including, but not limited to, the EzLoc™ Femoral Fixation Device with WasherLoc™ Tibial Fixation Device, the ToggleLoc™ Femoral Fixation Device, the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology, and the ZipTight™ Fixation System, are a material part of the apparatus of the '514 patent for at least the reason that such Biomet suture anchors are specially designed to embody and do embody the elements of at least claim 1 the '514 patent.
- 90. Defendants have induced and continue to induce the infringement of the '514 patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM

Tibial Fixation Device, the ToggleLoc[™] Femoral Fixation Device, the ToggleLoc[™] Femoral Fixation Device with ZipLoop[™] Technology, and the ZipTight[™] Fixation System, related instruments and products, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals in implanting such Biomet suture anchors, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, that encourage, promote, instruct, teach and induce implantation and use of such Biomet suture anchors that embody the elements of at least claim 1 of the '514 patent.

91. With knowledge of the '514 patent and the specific intent to encourage, promote, instruct, teach, induce and contribute to the infringement of the '514 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet suture anchors, including but not limited to, the EzLocTM Femoral Fixation Device with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, that embody the elements of at least claim 1 of the '514 patent, by: (1) creating, distributing, and supplying surgical technique guides and instructions for use including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, which encourage, promote, instruct, teach, contribute to and induce the use of such Biomet suture anchors that embody the elements of at least claim 1 of the '514 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or

instructing medical professionals in the use of suture anchor related instruments and products including specially designed instruments for use in implanting and use with such Biomet suture anchors that embody the elements of at least claim 1 of the '514 patent.

- 92. Medical professionals have infringed and continue to infringe the '514 patent, directly, indirectly, literally and by equivalents, by using in the United States Biomet suture anchors in the United States including, but not limited to, the EzLocTM with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System, that embody the elements of at least claim 1 of the '514 patent.
- 93. Defendants had and have actual and/or constructive knowledge of the infringement of the '514 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '514 patent, Defendants did make, sell, offer to sell, distribute, supply and/or import into the United States suture anchors that embody the elements of at least claim 1 of the '514 patent; Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, for Biomet suture anchors, including, but not limited to, the EzLocTM with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Technology, and the ZipTightTM Fixation System, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet suture anchors that embody the elements of at least claim 1 of the '514 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within

the United States and/or instruct medical professionals in the use of such Biomet suture anchors that are specially designed to embody the elements of at least claim 1 of the '514 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '514 patent as a result of the medical professionals use of Biomet suture anchors, including, but not limited to, the EzLocTM with WasherLocTM Tibial Fixation Device, the ToggleLocTM Femoral Fixation Device, the ToggleLocTM Femoral Fixation Device with ZipLoopTM Technology, and the ZipTightTM Fixation System with ZipLoopTM Technology, that embody the elements of at least claim 1 of the '514, and were willfully blind that the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the ACL Reconstruction, the Femoral Fixation for ACL Reconstruction, and the Ankle Syndesmosis surgical technique guides, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques and uses for Biomet suture anchors that embody the elements of at least claim 1 of the '514 patent.
- 95. Defendants' infringement of the '514 patent is and has been willful and deliberate.
- 96. Defendants knew of the '514 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT FOUR (4): INFRINGEMENT OF THE '073 PATENT

97. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.

- 98. Defendants have and had actual and/or constructive knowledge of the '073 patent.
- 99. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '073 patent, directly, indirectly, literally and/or equivalently.
- import within the United States Biomet suture anchors, including, but not limited to, the ALLthread ™ Knotless suture anchor. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the ALLthread ™ Knotless in a manner that practices at least the method of claims 35 and/or 39 of the '073 patent. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guide entitled the Double Row Rotator Cuff Repair, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the ALLthread ™ Knotless in a manner that practices at least the method of claims 35 and/or 39 of the '073 patent. By these actions, the Defendants with actual and/or constructive knowledge of the '073 patent, have infringed and continue to infringe at least claims 35 and/or 39 of the '073 patent, literally or equivalently.
- 101. Defendants have induced and continue to induce the infringement of the '073 patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet suture anchors, including, but not limited to, the ALLthread TM Knotless suture anchor, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing

related instruments and products for use by medical professionals in implanting such Biomet suture anchors, and (3) creating, distributing, and supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the Double Row Rotator Cuff Repair surgical technique guide, that encourage, promote, instruct, teach and induce implantation and use of such Biomet suture anchors with such instruments in a manner that practices the method of at least claims 35 and/or 39 of the '073 patent.

- 102. With knowledge of the '073 patent and the specific intent to encourage, promote, instruct, teach, and induce the infringement of the '073 patent, Defendants did encourage, promote, instruct, teach, and induce medical professionals to use within the United States Biomet suture anchors, including but not limited to, the ALLthread ™ Knotless suture anchor, and/or related instruments and products, in a manner that practices the method of at least claims 35 and/or 39 of the '073 patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use, including, but not limited to, the Double Row Rotator Cuff Repair surgical technique guide, that encourage, promote, instruct, teach, and induce the use of such Biomet suture anchors and/or related instruments and products in a manner that practices the method of at least claims 35 and/or 39 of the '073 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of suture anchor related instruments and products for use with such Biomet suture anchors that are specially designed for use in and are used in a manner that practices the method of at least claims 35 and/or 39 of the '073 patent.
- 103. Medical professionals have infringed and continue to infringe the '073 patent, directly, indirectly, literally and by equivalents, by using Biomet suture anchors, including, but not limited to, the ALLthread TM Knotless suture anchor, and/or related instruments and products

during surgeries in the United States in a manner that practices the method of at least claims 35 and /or 39 of the '073 patent.

- infringement of the '073 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '073 patent, Defendants did create and/or distribute, and have created and distributed instructions for use and surgical technique guides, including, but not limited to, the Double Row Rotator Cuff Repair, and/or suture anchor related instruments and products, that encourage, promote, instruct, teach, and/or induce the use of such Biomet suture anchors and/or related instruments and products in a manner that practices the method of at least claims 35 and/or 39 of the '073 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet suture anchors and/or related anchor related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claims 35 and/or 39 of the '073 patent.
- 105. At the very least, Defendants were willfully blind as to the existence of the '073 patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '073 patent as a result of the medical professionals use of Biomet suture anchors and related instruments, including but not limited to, the ALLthread ™ Knotless suture anchor, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, including but not limited to, the Double Row Rotator Cuff Repair surgical technique guide for the ALLthread ™ Knotless suture anchor, whereby such instructions and surgical technique guides encourage, promote, instruct, teach,

disclose and set forth techniques that practice the method of at least claims 35 and/or 39 of the '073 patent.

- 106. Defendants' infringement of the '073 patent is and has been willful and deliberate.
- 107. Defendants knew of the '073 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT FIVE (5): INFRINGEMENT OF THE '531 PATENT

- 108. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 109. Defendants have and had actual and/or constructive knowledge of the '531 patent.
- 110. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '531 patent, directly, indirectly, literally and/or equivalently.
- 111. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet bone spacers and wedges, including but not limited to, the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System in a manner that practices at least the method of claim 46 of the '531 patent. Defendants, among other things,

have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guide entitled the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System in a manner that practices at least the method of claim 46 of the '531 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '531 patent, have infringed and continue to infringe at least claim 46 of the '531 patent, literally or equivalently.

- 112. Defendants have contributed to and continue to contribute to the infringement of the '531 patent by selling, offering to sell, distributing, supplying, and/or importing Biomet bone spacers and wedges and/or related instruments, including but not limited to, the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System, and related instruments and products that are for use in a method that practices at least claim 46 of the '531 patent.

 Defendants further contributed to and continue to contribute to the infringement of the '531 patent by creating and/or distributing Biomet surgical technique guides, including, but not limited to, the surgical technique guide entitled SolitaireTM-C Cervical Spacer System, that promote, teach, instruct, disclose, set forth, demonstrate, encourage, and/or contribute to the implantation of the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System in a manner that practices the method of at least claim 46 of the '531 patent.
- 113. These Biomet bone spacers and wedges, including, but not limited to, the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System, and/or related instruments and products, are not staple articles or commodities of commerce suitable for substantial noninfringing use as, the bone spacers and wedges, and related instruments and

products are designed to be used only in a manner that infringes at least claim 46 of the '531 patent, and the instructions for use and surgical technique guides supplied by Biomet only teach one way to use such products and/or related instruments and products, and those techniques infringe at least claim 46 of the '531 patent.

- 114. Biomet bone spacers and wedges, including, but not limited to, the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System, and/or related instruments and products, are a material part of the method of the '531 patent for at least the reason that such bone spacers and wedges, and/or related instruments and products, are specially designed for use in and are used to practice the method of at least claim 46 of the '531 patent.
- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet bone spacers and wedges, including but not limited to, the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System, for use by medical professionals, (2) selling, offering to sell, distributing, supplying and/or importing related instruments and products for use by medical professionals in implanting such Biomet bone spacers and wedges, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guide, including, but not limited to, the SolitaireTM-C Cervical Spacer System surgical technique guide, that encourage, promote, instruct, teach, and induce implantation of such Biomet bone spacers and wedges with such instruments in a manner that practices the method of at least claim 46 of the '531 patent.
- 116. With knowledge of the '531 patent and the specific intent to encourage, promote, instruct, teach, contribute to, and induce the infringement of the '531 patent, Defendants did encourage, promote, instruct, teach, and contribute to, and induce medical professionals to use

within the United States Biomet bone spacers and wedges, including, but not limited to, the SolitaireTM-C Cervical Spacer System and SolitaireTM Anterior Spinal System, and/or related instruments and products, in a manner that practices the method of at least claim 46 of the '531 patent, by: (1) creating, distributing, and supplying surgical technique guides and instructions for use, including, but not limited to, the SolitaireTM-C Cervical Spacer System surgical technique guide, that encourage, promote, instruct, teach, contribute to, and induce the use of such Biomet bone spacers and wedges, and/or related instruments and products, in a manner that practices the method of at least claim 46 of the '531 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States, and/or instructing medical professionals in the use of bone spacer related instruments and products for use with such Biomet bone spacers and wedges that are specially designed for use in and are used in a manner that practices the method of at least claim 46 of the '531 patent.

- 117. Medical professionals have infringed and continue to infringe the '986 patent, directly, indirectly, literally and by equivalents, by using Biomet bone spacers and wedges, including, but not limited to, the SolitaireTM-C Cervical Spacer System and the SolitaireTM Anterior Spinal System, and/or related instruments and products during surgeries in the United States in a manner that practices the method of at least claim 46 of the '531 patent.
- 118. Defendants had and have actual and/or constructive knowledge of the infringement of the '531 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '531 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the SolitaireTM-C Cervical Spacer System surgical technique guide, for Biomet bone spacers and

wedges, including, but not limited to, the SolitaireTM-C Cervical Spacer System and the SolitaireTM Anterior Spinal System, and/or related instruments and products, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet bone spacers and wedges and/or related instruments and products in a manner that practices the method of at least claim 46 of the '531 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States, and/or instruct medical professionals in the use of such Biomet bone spacers and wedges, and/or related instruments and products, that are specially designed for use in and are used in a manner that practices the method of at least claim 46 of the '531 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '531 patent as a result of the medical professionals use of Biomet bone spacers and wedges and related instruments, including, but not limited to, the SolitaireTM-C Cervical Spacer System and the SolitaireTM Anterior Spinal System, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the SolitaireTM-C Cervical Spacer System surgical technique guide, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice method of at least claim 46 of the '531 patent.
- 120. Defendants' infringement of the '531 patent is and has been willful and deliberate.

121. Defendants knew of the '531 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT SIX (6): INFRINGEMENT OF THE '063 PATENT

- 122. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 123. Defendants have and had actual and/or constructive knowledge of the '063 patent.
- 124. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '063 patent, directly, indirectly, literally and/or equivalently.
- import within the United States Biomet bone spacers and wedges, including but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting Biomet bone spacers and wedges, including, but not limited to the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, in a manner that practices at least the method of claim 1 of the '063 patent. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System in the manner that practices at least

the method of claim 1 of the '063 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '063 patent, have infringed and continue to infringe at least claim 1 of the '063 patent, literally or equivalently.

- 126. Defendants have contributed to and continue to contribute to the infringement of the '063 patent by selling, offering to sell, distributing, supplying, and/or importing Biomet bone spacers and wedges, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, and related instruments and products, that are for use in a method that practices at least claim 1 of the '063 patent. Defendants further contributed to, and continue to contribute to the infringement of the '063 patent by creating and/or distributing Biomet surgical technique guides, including, but not limited to, surgical technique guides entitled OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, that promote, teach, instruct, disclose, set forth, demonstrate, encourage, and/or contribute to the implantation of the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System in a manner that practices the method of at least claim 1 of the '063 patent.
- OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, and/or related instruments and products, are not staple articles or commodities of commerce suitable for substantial noninfringing use as, such bone spacers and wedges, and related instruments and products are designed to be used in a manner that infringes at least claim 1 of the '063 patent, and all the instructions for use and surgical technique guides supplied by Biomet only teach one way to use such products and/or related instruments and products, and those techniques infringe at least claim 1 of the '063 patent.

- 128. Biomet bone spacers and wedges, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, and/or related instruments and products, are a material part of the method of the '063 patent for at least the reason that such bone spacers and wedges, and/or related instruments and products, are specially designed for use in and are used to practice the method of at least claim 1 of the '063 patent.
- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet bone spacers and wedges, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals in implanting such Biomet bone spacers and wedges, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, and/or related instruments and products, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System surgical technique guides, that encourage, promote, instruct, teach, and induce implantation of such Biomet bone spacer and wedges with such instruments in a manner that practices the method of at least claim 1 of the '063 patent.
- 130. With knowledge of the '063 patent and the specific intent to encourage, promote, instruct, teach, contribute to, and induce the infringement of the '063 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet bone spacers and wedges, including but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, and/or related instruments and products, in a manner that practices the method of at least claim 1 of the '063

patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System surgical technique guides, that encourage, promote, instruct, teach, contribute to, and induce the use of such Biomet bone spacers and wedges and/or related instruments and products in a manner that practices the method of at least claim 1 of the '063 patent; (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of bone wedge related instruments and products for use with such Biomet bone spacers and wedges that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '063 patent.

- 131. Medical professionals have infringed and continue to infringe the '063 patent, directly, indirectly, literally and by equivalents, by using Biomet bone spacers and wedges, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, and/or related instruments and products during surgeries in the United States in a manner that practices the method of at least claim 1 of the '063 patent.
- 132. Defendants had and have actual and/or constructive knowledge of the infringement of the '063 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '063 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System surgical technique guides, for Biomet bone spacers and wedges, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System,

and/or related instruments and products, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet bone spacers and wedges and/or related instruments and products in a manner that practices the method of at least claim 1 of the '063 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet bone spacers and wedges and/or related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '063 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '063 patent as a result of the medical professionals use of Biomet bone spacers and wedges and related instruments, including, but not limited to, the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the OsteoStim® Cervical Allograft System and the OsteoStim® PLIF Allograft Spacer System technique guides, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice method of at least claim 1 of the '063 patent.
- 134. Defendants' infringement of the '063 patent is and has been willful and deliberate.
- 135. Defendants knew of the '063 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT SEVEN (7): INFRINGEMENT OF THE '821 PATENT

- 136. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 137. Defendants have and had actual and/or constructive knowledge of the '821 patent.
- 138. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '821 patent, directly, indirectly, literally and/or equivalently.
- import within the United States Biomet knee systems, including but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System in a manner that practices at least the method of claims 1 and/or 8 of the '821 patent. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled the Oxford® Partial Knee and the Vanguard MTM Partial Knee Lateral and Medial, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System in a manner that practices at least the method of claims 1 and/or 8 of the '821 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '821 patent, have

infringed and continue to infringe at least claims 1 and/or 8 of the '821 patent, literally or equivalently.

- 140. Defendants have contributed to and continue to contribute to the infringement of the '821 patent by selling, offering to sell, supplying, and/or importing Biomet knee systems, including, but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, and related instruments and products, that are for use in a method that practices at least claims 1 and/or 8 of the '821 patent. Defendants further contributed to and continue to contribute to the infringement of the '821 patent by creating and/or distributing Biomet surgical technique guides, including, but not limited to, the Oxford® Partial Knee and the Vanguard MTM Partial Knee Lateral and Medial surgical technique guides, that promote, teach, instruct, disclose, set form, demonstrate, encourage and/or contribute to the implantation of the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent.
- 141. These Biomet knee systems, including, but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, and/or related instruments and products, are not staple articles or commodities of commerce suitable for substantial noninfringing use as, such knee systems and related instruments and products are designed to be used in a manner that infringes at least claims 1 and/or 8 of the '821 patent, and all the instructions for use and surgical technique guides supplied by Biomet only teach one way to use such products and/or related instruments and products, and those techniques infringe at least claims 1 and/or 8 of the '821 patent.

- 142. Biomet knee systems, including, but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, and/or related instruments and products, are a material part of the method of the '821 patent for at least the reason that such knee systems, and/or related instruments and products, are specially designed for use in and are used to practice the method of at least claims 1 and/or 8 of the '821 patent.
- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet knee systems, including, but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals in implanting such Biomet Knee Systems, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the Oxford® Partial Knee and the Vanguard MTM Partial Knee Lateral and Medial surgical technique guides, that encourage, promote, instruct, teach, and induce the use of such Biomet knee systems with such instruments in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent.
- 144. With knowledge of the '821 patent and the specific intent to encourage, promote, instruct, teach, contribute to, and induce the infringement of the '821 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet knee systems, including, but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, and/or related Biomet instruments and products, in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent, by (1) creating, distributing, and/or supplying surgical technique guides and instructions for use,

including, but not limited to, the Oxford® Partial Knee and the Vanguard MTM Partial Knee

Lateral and Medial Surgical technique guides, that encourage, promote, instruct, teach,
contribute to and induce the use of such Biomet knee systems, and/or related instruments and
products, in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent;
and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing
within the United States, and/or instructing medical professionals in the use of knee system
related instruments and products for use with such Biomet knee systems that are specially
designed for use in and are used in a manner that practices the method of at least claims 1 and/or
8 of the '821 patent.

- 145. Medical professionals have infringed and continue to infringe the '821 patent, directly, indirectly, literally and by equivalents, by using Biomet knee systems, including, but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, and/or related instruments and products, during surgeries in the United States in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent.
- 146. Defendants had and have actual and/or constructive knowledge of the infringement of the '821 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '821 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the Oxford® Partial Knee and the Vanguard MTM Partial Knee Lateral and Medial surgical technique guides, for Biomet knee systems, including but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, and/or related instruments and products, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet knee

systems and/or related instruments and products in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet knee systems and/or related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claims 1 and/or 8 of the '821 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '821 patent as a result of the medical professionals use of Biomet knee systems and related instruments in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, including but not limited to, the Oxford® Partial Knee System and the Vanguard MTM Partial Knee System, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claims 1 and/or 8 of the '821 patent.
- 148. Defendants' infringement of the '821 patent is and has been willful and deliberate.
- 149. Defendants knew of the '821 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT EIGHT (8): INFRINGEMENT OF THE '996 PATENT

150. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.

- 151. Defendants have and had actual and/or constructive knowledge of the '996 patent.
- 152. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '996 patent, directly, indirectly, literally and/or equivalently.
- 153. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet knee systems, including, but not limited to, the VanguardTM SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with PremierTM Total Knee Instrumentation. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for implanting the Vanguard™ SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with PremierTM Total Knee Instrumentation that embody the elements of at least claim 1 of the '996 patent. Defendants, among other things, have created and distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled the PremierTM Total Knee Instrumentation, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the Vanguard™ SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with Premier™ Total Knee Instrumentation using instrumentation that embodies the elements of at least claim 1 of the '996 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '996 patent, have infringed and continue to infringe at least claim 1 of the '996 patent, literally or equivalently.

- 154. Defendants have contributed and continue to contribute to the infringement of the '996 patent by selling, offering to sell, supplying, and/or importing Biomet knee systems, including, but not limited to, the Vanguard™ SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with Premier™ Total Knee Instrumentation, and related instruments and products, that embody the elements of at least claim 1 of the '996 patent. Defendants further contributed to and continue to contribute to the infringement of the '996 patent by creating and/or distributing Biomet surgical technique guides, including, but not limited to, the surgical technique guide entitled the Premier™ Total Knee Instrumentation that promotes, encourages and teaches the use and implantation of such knee systems with instrumentation that embodies the elements of at least claim 1 of the '996 patent.
- 155. These Biomet knee systems, including but not limited to, the Vanguard™ SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with Premier™ Total Knee Instrumentation, and/or especially the related instruments for implantation, are not staple articles or commodities of commerce suitable for substantial noninfringing use as the instrumentation, including especially the cutting guides, embody the elements of at least claim 1 of the '996 patent and thus those guides infringe at least claim 1 of the '996 patent.
- 156. Biomet knee systems, including but not limited to, the VanguardTM SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with PremierTM Total Knee Instrumentation, and/or related instruments and products including especially the cutting guides for such knee systems, are a material part of the invention of the '996 patent for at least the reason that such knee systems, and/or related instruments and

products are specially designed to embody and do embody the elements of at least claim 1 of the '996 patent.

- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet knee systems, including but not limited to, the VanguardTM SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with PremierTM Total Knee Instrumentation for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products, including the PremierTM Total Knee Instrumentation and especially the cutting guides, for use by medical professionals in implanting the Biomet knee systems, and (3) creating, distributing, and supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the PremierTM Total Knee Instrumentation surgical technique guide, that encourage, promote, instruct, teach and induce implantation and use of the Biomet knee systems including the use of cutting guides that embody the elements of at least claim 1 of the '996 patent.
- 158. With knowledge of the '996 patent and the specific intent to encourage, promote, instruct, teach, induce and contribute to the infringement of the '996 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet knee systems, including, but not limited to, the VanguardTM SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with PremierTM Total Knee Instrumentation, and/or related instruments and products, including cutting guides that embody the apparatus of at least claim 1 of the '996 patent, by: (1) creating, distributing, and supplying surgical technique guides and instructions for use including, but not limited to, the PremierTM Total Knee Instrumentation technique guides, which encourage,

promote, instruct, teach, contribute to and induce the use of such Biomet knee systems, and/or related instruments and products that instruct the use of such Biomet knee systems, and/or related instruments and products that embody the apparatus of at least claim 1 of the '996 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing into the United States and/or instructing medical professionals in the use of knee system related instruments and products for use with such Biomet knee systems that are specially designed for use in and are used in implanting such Biomet knee systems, whereby the specially designed cutting guide instruments embody the elements of at least claim 1 of the '996 patent.

- 159. Medical professionals have infringed and continue to infringe the '996 patent, directly, indirectly, literally and by equivalents, by using Biomet knee systems, including but not limited to, the VanguardTM SSK Revision System, the Vanguard 360® Revision Knee System, and Vanguard Complete Knee System with PremierTM Total Knee Instrumentation, and/or related instruments including the cutting guides, during surgeries in the United States, that embody the elements of at least claim 1 of the '996 patent.
- 160. Defendants had and have actual and/or constructive knowledge of the infringement of the '996 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '996 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the Premier™ Total Knee Instrumentation, for Biomet knee systems, including but not limited to, the Vanguard™ SSK Revision System, the Vanguard 360® Revision Knee System, and the Vanguard Complete Knee System with Premier™ Total Knee Instrumentation, and/or related instruments and products such as cutting guides, that encourage, promote, instruct, teach,

contribute to, and/or induce the use of such Biomet knee systems, and/or related instruments and products, that embody the elements of at least claim 1 of the '996 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States, and/or instruct medical professionals in the use of such Biomet knee systems and/or knee system related instruments that embody the elements of at least claim 1 of the '996 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '996 patent as a result of the medical professionals use of Biomet knee systems and instruments, including but not limited to, the VanguardTM SSK Revision System, the Vanguard 360® Revision Knee System, and the Vanguard Complete Knee System with PremierTM Total Knee Instrumentation, including cutting guides that embody the elements of claim 1 of the '996 patent, and medical professionals use of techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the PremierTM Total Knee Instrumentation surgical technique guide, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, and set forth techniques that use instruments that embody the elements of at least claim 1 of the '996 patent.
- 162. Defendants' infringement of the '996 patent is and has been willful and deliberate.
- 163. Defendants knew of the '996 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT NINE (9): INFRINGEMENT OF THE '740 PATENT

- 164. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 165. Defendants have and had actual and/or constructive knowledge of the '740 patent.
- 166. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '740 patent, directly, indirectly, literally and/or equivalently.
- 167. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products, such as for example the Premier Total Knee Instrumentation, designed and specially adapted for implanting the Vanguard® Complete Knee System (CR or PS) in a manner that practices at least the method of claim 20 of the '740 patent. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guide entitled the Premier® Total Knee Instrumentation, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the Vanguard® Complete Knee System (CR or PS) in a manner that practices at least the method of claim 20 of the '740 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '740 patent, have infringed and continue to infringe at least claim 20 of the '740 patent, literally or equivalently.

- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, and/or related Biomet instruments and products, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products, including the Premier® Total Knee Instrumentation, for use by medical professionals in implanting the Biomet Vanguard® Complete Knee System (CR or PS), and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the Premier™ Total Knee Instrumentation surgical technique guide, that encourage, promote, instruct, teach and induce implantation of such Biomet knee systems in a manner that practices the method of at least claim 20 of the '740 patent.
- 169. With knowledge of the '740 patent and the specific intent to encourage, promote, instruct, teach, and induce the infringement of the '740 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, and/or related instruments and products, in a manner that practices the method of at least claim 20 of the '740 patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use including, but not limited to, the Premier® Total Knee Instrumentation surgical technique guide, that encourage, promote, instruct, teach, and induce the use of such Biomet knee systems, and the related Premier™ Total Knee Instrumentation, in a manner that practices the method of at least claim 20 of the '740 patent; and, (2) designing, manufacturing, offering for sale, selling,

distributing, supplying, importing within the United States and/or instructing medical professionals in the use of the Premier® Total Knee Instrumentation that are specially designed for use in and are used in a manner that practices the method of at least claim 20 of the '740 patent.

- 170. Medical professionals have infringed and continue to infringe the '740 patent, directly, indirectly, literally and by equivalents, by using Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, and/or related instruments such as the PremierTM Total Knee Instrumentation, during surgeries in the United States in a manner that practices the method of at least claim 20 of the '740 patent.
- infringement of the '740 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '740 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the Premier® Total Knee Instrumentation surgical technique guides, for Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) that encourage, promote, instruct, teach, and/or induce the use of such Biomet knee systems and/or related instruments in a manner that practices the method of at least claim 20 of the '740 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet knee systems and/or knee system related instruments that are specially designed for use in and are used in a manner that practices the method of at least claim 20 of the '740 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '740 patent as a result of the medical professionals use of Biomet knee systems and related instruments, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the Premier® Total Knee Instrumentation technique guide, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claim 20 of the '740 patent.
- 173. Defendants' infringement of the '740 patent is and has been willful and deliberate.
- 174. Defendants knew of the '740 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT TEN (10): INFRINGEMENT OF THE '896 PATENT

- 175. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 176. Defendants have and had actual and/or constructive knowledge of the '896 patent.
- 177. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '896 patent, directly, indirectly, literally and/or equivalently.

178. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet knee systems, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States instruments and products such as the SignatureTM Personalized Patient Care System designed and specially adapted for implanting the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System in a manner that practices at least the method of claims 1 and/or 40 of the '896 patent. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled the SignatureTM Personalized Patient Care Utilized with the Oxford® Partial Knee and the Vanguard® Complete Knee System, the SignatureTM Personalized Patient Care Surgical Technique Addendum: Oxford® Partial Knee, and the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Vanguard® Complete Knee System, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System and the Signature™ Personalized Patient Care System using the Vanguard® Complete Knee System in the manner that practices at least the method of claims 1 and/or 40 of the '896 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '896 patent, have infringed and continue to infringe at least claims 1 and/or 40 of the '896 patent, literally or equivalently

- 179. Defendants have contributed to and continue to contribute to the infringement of the '896 patent by selling, offering to sell, supplying, and/or importing Biomet knee systems, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, that are for use in a method that practices at least claims 1 and/or 40 of the '896 patent. Defendants further contributed to the infringement of the '896 patent by creating and/or distributing surgical technique guides, including, but not limited to, the SignatureTM Personalized Patient Care Utilized with the Oxford® Partial Knee and the Vanguard® Complete Knee System, the Signature™ Personalized Patient Care Surgical Technique Addendum: the Oxford® Partial Knee, and the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Vanguard® Complete Knee System surgical technique guides, that promote, teach, instruct, disclose, set forth, demonstrate, encourage and/or contribute to the implantation of the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, in a manner that practices the method of at least claims 1 and/or 40 of the '896 patent.
- 180. These Biomet knee systems and/or related instruments and products, including but not limited to, the Signature™ Personalized Patient Care System using the Oxford® Partial Knee System, and the Signature™ Personalized Patient Care System using the Vanguard® Complete Knee System, are not staple articles or commodities of commerce suitable for substantial noninfringing use, such knee systems and related instruments and products are designed to be used only in a manner that infringes at least claims 1 and/or 40 of the '896 patent, and as all the instructions for use and surgical technique guides supplied by Biomet only teach

one way to use such knee systems and/or related instruments, and those techniques infringe at least claims 1 and/or 40 of the '896 patent.

- Biomet knee systems and/or related instruments and products, including, but not limited to, the Signature[™] Personalized Patient Care System using the Oxford® Partial Knee System, and the Signature[™] Personalized Patient Care System using the Vanguard® Complete Knee System, are a material part of the method of the '896 patent for at least the reason that such knee systems, and/or related instruments and products, are specially designed for use in and are used to practice the method of at least claims 1 and/or 40 of the '896 patent.
- 182. Defendants have induced and continue to induce the infringement of the '896 patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet knee systems, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the Signature™ Personalized Patient Care System using the Vanguard® Complete Knee System, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products, such as the SignatureTM Personalized Patient Care System, for use by medical professionals in implanting the Biomet SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the SignatureTM Personalized Patient Care Utilized with the Oxford® Partial Knee and the Vanguard® Complete Knee System, the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Oxford® Partial Knee, and the Signature™ Personalized Patient Care Surgical Technique Addendum: the Vanguard® Complete Knee System surgical technique guides, that encourage, promote, instruct,

teach and induce implantation of the Biomet Signature[™] Personalized Patient Care System using the Oxford® Partial Knee System, and the Signature[™] Personalized Patient Care System using the Vanguard® Complete Knee System in a manner that practices the method of at least claims 1 and/or 40 of the '896 patent.

With knowledge of the '896 patent and the specific intent to encourage, promote, 183. instruct, teach, contribute and/or induce to the infringement of the '896 patent, Defendants did encourage, promote, instruct, teach, contribute to, and induce medical professionals to use within the United States Biomet knee systems, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, and/or related instruments and products, such as the SignatureTM Personalized Patient Care System, in a manner that practices the method of at least claims 1 and/or 40 of the '896 patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use, including, but not limited to, the Signature™ Personalized Patient Care Utilized with the Oxford® Partial Knee and the Vanguard® Complete Knee System, the Signature™ Personalized Patient Care Surgical Technique Addendum: Oxford® Partial Knee, and the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Vanguard® Complete Knee System surgical technique guides, that encourage, promote, instruct, teach, contribute to and induce the use of such Biomet knee systems and/or related instruments and products in a manner that practices the method of at least claim 40 of the '896 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of knee system and related instruments and products, such as the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the

SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, that are specially designed for use in and are used in a manner that practices the method of at least claims 1 and/or 40 of the '896 patent.

- 184. Medical professionals have infringed and continue to infringe the '896 patent, directly, indirectly, literally and by equivalents, by using Biomet knee systems, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, and/or related instruments and products, such as the SignatureTM Personalized Patient Care System, during surgeries in the United States in a manner that practices the method of at least claim 40 of the '896 patent.
- infringement of the '896 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '896 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the SignatureTM Personalized Patient Care Utilized with the Oxford® Partial Knee and the Vanguard® Complete Knee System, the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Oxford® Partial Knee, and the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Vanguard® Complete Knee System surgical technique guides, for Biomet knee systems, and/or related instruments and products, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, that encourage, promote, instruct, teach, contribute to, and/or induce the use of

such Biomet knee systems, and/or related instruments and products, in a manner that practices the method of at least claims 1 and/or 40 of the '896 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet knee systems and/or knee system related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claims 1 and/or 40 of the '896 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '896 patent as a result of the medical professionals use of Biomet knee systems and related insertion instruments, including, but not limited to, the SignatureTM Personalized Patient Care System using the Oxford® Partial Knee System, and the SignatureTM Personalized Patient Care System using the Vanguard® Complete Knee System, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the SignatureTM Personalized Patient Care Utilized with the Oxford® Partial Knee and the Vanguard® Complete Knee System, the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Oxford® Partial Knee, and the SignatureTM Personalized Patient Care Surgical Technique Addendum: the Vanguard® Complete Knee System surgical technique guides, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claims 1 and/or 40 of the '896 patent.
- 187. Defendants' infringement of the '896 patent is and has been willful and deliberate.

188. Defendants knew of the '896 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT ELEVEN (11): INFRINGEMENT OF THE '897 PATENT

- 189. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 190. Defendants have and had actual and/or constructive knowledge of the '897 patent.
- 191. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '897 patent, directly, indirectly, literally and/or equivalently.
- 192. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products such as the Premier™ Total Knee Instrumentation designed and specially adapted for implanting the Vanguard® Complete Knee System (CR or PS) in a manner that practices at least the method of claim 1 of the '897 patent. Defendants, among other things, have created and distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled the Premier® Total Knee Instrumentation, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of the Vanguard® Complete Knee System (CR or PS) with Premier®

Total Knee Instrumentation in a manner that practices at least the method of claim 1 of the '897 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '897 patent, have infringed and continue to infringe at least claim 1 of the '897 patent, literally or equivalently.

- patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products, such as the Premier® Total Knee Instrumentation, for use by medical professionals in implanting the Biomet the Vanguard® Complete Knee System (CR or PS), and (3)creating, distributing, and supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the Premier® Total Knee Instrumentation surgical technique guide, that encourage, promote, instruct, teach and induce implantation of the Biomet the Vanguard® Complete Knee System (CR or PS) in a manner that practices the method of at least claim 1 of the '897 patent.
- 194. With knowledge of the '897 patent and the specific intent to encourage, promote, instruct, teach, and/or induce the infringement of the '897 patent, Defendants did encourage, promote, instruct, teach, and/or induce medical professionals to use within the United States Biomet knee systems, including but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, and/or related instruments and products, such as the Premier® Total Knee Instrumentation, in a manner that practices the method of at least claim 1 of the '897 patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use, including, but not limited to, the Premier® Total Knee

Instrumentation surgical technique guide, that encourage, promote, instruct, teach, and/or induce the use of such Biomet knee systems and/or related instruments and products in a manner that practices the method of at least claim 1 of the '897 patent; and (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of knee system and related instruments and products, such as the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '897 patent.

- 195. Medical professionals have infringed and continue to infringe the '897 patent, directly, indirectly, literally and by equivalents, by using Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, and/or related instruments and products such as the Premier® Total Knee Instrumentation, during surgeries in the United States in a manner that practices the method of at least claim 1 of the '897 patent.
- 196. Defendants had and have actual and/or constructive knowledge of the infringement of the '897 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '897 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the Premier® Total Knee Instrumentation surgical technique guide, for Biomet knee systems and/or related instruments and products including but not limited to, the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, that encourage, promote, instruct, teach, and/or induce the use of such Biomet knee systems, and/or related instruments

and products, in a manner that practices the method of at least claim 1 of the '897 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet knee systems and/or knee system related instruments and products, such as the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '897 patent.

- patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '897 patent as a result of the medical professionals use of Biomet knee systems and related instruments, such as the Vanguard® Complete Knee System (CR or PS) with Premier® Total Knee Instrumentation, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides, such as the Premier™ Total Knee Instrumentation for such products, whereby such instructions and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claim 1 of the '897 patent.
- 198. Defendants' infringement of the '897 patent is and has been willful and deliberate.
- 199. Defendants knew of the '897 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT TWELVE (12): INFRINGEMENT OF THE '229

- 200. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 201. Defendants have and had actual and/or constructive knowledge of the '229 patent.
- 202. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '229 patent, directly, indirectly, literally and/or equivalently.
- 203. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System with the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation or the Microplasty® Elite Total Knee Instrumentation. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products, such as the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total Knee Instrumentation, designed and specially adapted for implanting the Vanguard® Complete Knee System in a manner that practices at least the method of claim 1 of the '229 patent. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the surgical technique guides entitled the Premier® Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation, and the Microplasty® Elite Total Knee Instrumentation surgical technique guides, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, and/or induce the implantation of the Vanguard® Complete Knee

System in a manner that practices at least the method of claim 1 of the '229 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '229 patent, have infringed and continue to infringe at least claim 1 of the '229 patent, literally or equivalently.

Defendants have induced and continue to induce the infringement of the '229 204. patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System with the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total Knee Instrumentation for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products, such as the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total Knee Instrumentation, for use by medical professionals in implanting the Biomet Vanguard® Complete Knee System, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total Knee Instrumentation surgical technique guides, that encourage, promote, instruct, teach and induce implantation of the Biomet Vanguard® Complete Knee System in a manner that practices the method of at least claim 1 of the '229 patent.

205. With knowledge of the '229 patent and the specific intent to encourage, promote, instruct, teach, and/or to induce the infringement of the '229 patent, Defendants did encourage, promote, instruct, teach, and induce medical professionals to use within the United States Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System, and/or related instruments and products, such as, the PremierTM Total Knee Instrumentation, the

Microplasty® Total Knee Instrumentation, and the Microplasty® Elite Total Knee
Instrumentation in a manner that practices the method of at least claim 1 of the '229 patent, by:

(1) creating, distributing, and supplying surgical technique guides and instructions for use,
including, but not limited to, the Premier® Total Knee Instrumentation, the Microplasty® Total
Knee Instrumentation, and the Microplasty® Elite Total Knee Instrumentation surgical technique
guides, that encourage, promote, instruct, teach, and induce the use of such Biomet knee systems
and/or related instruments and products in a manner that practices the method of at least claim 1
of the '229 patent; and (2) designing, manufacturing, offering for sale, selling, distributing,
supplying, importing within the United States and/or instructing medical professionals in the use
of knee system related instruments and products, such as the Premier™ Total Knee
Instrumentation, the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total
Knee Instrumentation, for use with such Biomet knee systems that are specially designed for use
in and are used in a manner that practices the method of at least claim 1 of the '229 patent.

- 206. Medical professionals have infringed and continue to infringe the '229 patent, directly, indirectly, literally and by equivalents, by using Biomet knee systems, including, but not limited to, the Vanguard® Complete Knee System, and/or related instruments and products such as such as the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation, and the Microplasty® Elite Total Knee Instrumentation, during surgeries in the United States in a manner that practices the method of at least claim 1 of the '229 patent.
- 207. Defendants had and have actual and/or constructive knowledge of the infringement of the '229 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '229 patent, Defendants did create and/or distribute, and have created and/or

distributed instructions for use and surgical technique guides, including, but not limited to, the Premier® Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation, and the Microplasty® Elite Total Knee Instrumentation surgical technique guides, for Biomet knee systems and/or related instruments and products, including, but not limited to, the Vanguard® Complete Knee System with the Premier™ Total Knee Instrumentation, Microplasty® Total Knee Instrumentation or the Microplasty® Elite Total Knee Instrumentation, that encourage, promote, instruct, teach, and/or induce the use of such Biomet knee systems, and/or related instruments and products in a manner that practices the method of at least claim 1 of the '229 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet knee systems and/or related knee system related instruments and products that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '229 patent.

208. At the very least, Defendants were willfully blind as to the existence of the '229 patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '229 patent as a result of the medical professionals use of Biomet knee systems and related instruments, such as the Vanguard® Complete Knee System with the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total Knee Instrumentation, in a manner that follows the methods and techniques set forth in Biomet's instructions for use and surgical technique guides for such products, such as the PremierTM Total Knee Instrumentation, the Microplasty® Total Knee Instrumentation and the Microplasty® Elite Total Knee Instrumentation surgical technique guides, whereby such instructions and surgical technique guides encourage, promote,

instruct, teach, disclose and set forth techniques that practice the method of at least claim 1 of the '229 patent.

- 209. Defendants' infringement of the '229 patent is and has been willful and deliberate.
- 210. Defendants knew of the '229 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT THIRTEEN (13): INFRINGEMENT OF THE '557 PATENT

- 211. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 212. Defendants have and had actual and/or constructive knowledge of the '557 patent.
- 213. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '557 patent, directly, indirectly, literally and/or equivalently.
- 214. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet tissue harvesting systems and tissue graft material, including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for preparing tissue graft material in a manner that practices at least the method of claim 1 of the '557 patent. Defendants, among other things, have created and/or distributed

instructions for use and surgical technique guides for the BioCUETM Platelet Concentration

System and the Bonus TM Demineralized Bone Matrix, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation of tissue graft material, including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix in a manner that practices at least the method of claim 1 of the '557 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '557 patent, have infringed and continue to infringe at least claim 1 of the '557 patent, literally or equivalently.

- 215. Defendants have induced and continue to induce the infringement of the '557 patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet tissue harvesting systems, and tissue graft material, including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals, in making, using and for harvesting and/or implanting tissue graft material, and (3) creating, distributing, and/or supplying medical professionals with Biomet surgical technique guides and brochures, including, but not limited, to the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix brochures that encourage, promote, instruct, teach and induce the use of such Biomet tissue harvesting systems and tissue graft material in a manner that practices the method of at least claim 1 of the '557 patent.
- 216. With knowledge of the '557 patent and the specific intent to encourage, promote, instruct, teach, and/or induce the infringement of the '557 patent, Defendants did encourage, promote, instruct, teach, contribute to, and/or induce medical professionals to use within the

United States Biomet tissue harvesting systems and tissue graft material, including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix, and/or related instruments and products, in a manner that practices the method of at least claim 1 of the '557 patent, by: (1) creating, distributing, and supplying surgical technique guides, brochures and instructions including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix brochures, that encourage, promote, instruct, teach, contribute to and induce the use of such Biomet tissue harvesting systems and tissue graft material, and/or related instruments and products in a manner that practices the method of at least claim 1 of the '557 patent; and (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of tissue harvesting related instruments and products, for use with such Biomet tissue harvesting systems and tissue graft material that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '557 patent.

- 217. Medical professionals have infringed and continue to infringe the '557 patent, directly, indirectly, literally and by equivalents, by using Biomet tissue harvesting systems, and tissue graft material, including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix, and/or related instruments and products, during surgeries in the United States in a manner that practices the method of at least claim 1 of the '557 patent.
- 218. Defendants had and have actual and/or constructive knowledge of the infringement of the '557 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive

knowledge of the '557 patent, Defendants did create and/or distribute, and have created and/or distributed instructions for use, brochures and surgical technique guides, including but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix brochures, for Biomet tissue harvesting systems, and tissue graft material and/or related instruments and products,, including, but not limited to, the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet tissue harvesting systems and/or related instruments and products in a manner that practices the method of at least claim 1 of the '557 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of such Biomet tissue harvesting systems and tissue graft material, and/or tissue harvesting and implantation related instruments and products, that are specially designed for use in and are used in a manner that practices the method of at least claim 1 of the '557 patent.

219. At the very least, Defendants were willfully blind as to the existence of the '557 patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '557 patent as a result of the medical professionals use of Biomet tissue harvesting systems, tissue graft material, and related products, including the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix, in a manner that follows the methods and techniques set forth in Biomet's instructions for use, brochures and surgical technique guides for such products, including the BioCUETM Platelet Concentration System and the Bonus TM Demineralized Bone Matrix brochures, whereby such instructions, brochures and surgical technique guides encourage, promote, instruct, teach, disclose and set forth techniques that practice the method of at least claim 1 of the '557 patent.

- 220. Defendants' infringement of the '557 patent is and has been willful and deliberate.
- 221. Defendants knew of the '557 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT FOURTEEN (14): INFRINGEMENT OF THE '852 PATENT

- 222. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 223. Defendants have and had actual and/or constructive knowledge of the '852 patent.
- 224. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '852 patent, directly, indirectly, literally and/or equivalently.
- 225. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States Biomet hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells that embody the elements of at least claims 34 and/or 43 of the '852 patent. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for medical professionals to implant and use the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not

limited to, the surgical technique guides entitled the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation and use of the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells that embody the elements of at least claims 34 and/or 43 of the '852 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '852 patent, have infringed and continue to infringe at least claims 34 and/or 43 of the '852 patent, literally or equivalently.

- 226. Defendants have contributed and continue to contribute to the infringement of the '852 patent by selling, offering to sell, supplying, and/or importing Biomet hip implants, including, but not limited to, the REGENEREX™ RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells that embody the elements of at least claims 34 and/or 43 of the '852 patent. Defendants further have contributed to and continue to contribute to the infringement of the '852 patent by designing, making, offering to sell, selling, distributing, supplying and/or importing into the United States instruments specially designed and adapted to implant and assist in the use of Biomet hip implants, such as the REGENEREX™ RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, and further by creating and/or distributing surgical technique guides, such as the REGENEREX™ RINGLOC® + Modular Acetabular System surgical technique guide, that promote, teach, instruct, and encourage the use of such Biomet hip implants that embody the elements of at least claim 34 and/or 43 of the '852 patent.
- 227. These Biomet hip implants, including, but not limited to, the REGENEREXTM
 RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, are
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not staple articles or commodities of commerce suitable for substantial noninfringing use as they embody the elements of at least claims 34 and/or 43 of the '852 patent.

- 228. Biomet hip implants, including, but not limited to, the REGENEREXTM
 RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells,
 and/or related instruments and products are a material part of the invention of the '852 patent for
 at least the reason that such hip implants embody the elements of at least claims 34 and/or 43 of
 the '852 patent, and/or the related instruments and products are specially designed to assist in the
 use and implantation of such Biomet hip implants.
- 229. Defendants have induced and continue to induce the infringement of the '996 patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet hip implants, including, but not limited to, the REGENEREX™ RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, and/or related instruments and products, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals in using and implanting such Biomet hip implants, and (3) creating, distributing, and supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the REGENEREX™ RINGLOC® + Modular Acetabular System surgical technique guide, that encourage, promote, instruct, teach and induce implantation of Biomet hip implant, such as the REGENEREX™ RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the elements of at least claims 34 and/or 43 of the '852 patent.
- 230. With knowledge of the '852 patent and the specific intent to encourage, promote, instruct, teach, induce and/or contribute to the infringement of the '852 patent, Defendants did

encourage, promote, instruct, teach, contribute to, and/or induce medical professionals to use within the United States Biomet hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the apparatus of at least claims 34 and/or 43 of the '852 patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, that encourage, promote, instruct, teach, contribute to and induce the use of such Biomet hip implants that embody the elements of at least claims 34 and/or 43 of the '852 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of hip implant related instruments and products for use with and for implanting such Biomet hip implants that are specially designed for use in implanting such Biomet hip implants that embody the elements of at least claims 34 and/or 43 of the '852 patent.

- 231. Medical professionals have infringed and continue to infringe the '852 patent, directly, indirectly, literally and by equivalents, by using in the United States Biomet hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the apparatus of at least claims 34 and/or 43 of the '852 patent.
- 232. Defendants had and have actual and/or constructive knowledge of the infringement of the '852 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '852 patent, Defendants did make, offer to sell, sell, distribute, supply and/or import into the United States Biomet hip implants, including, but not limited to the

REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision

Acetabular Shells that embody the elements of at least claims 34 and/or 43 of the '852 patent;

Defendants did create and/or distribute, and have created and/or distributed instructions for use and surgical technique guides entitled the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, for such Biomet hip implants, and/or related instruments and products, that encourage, promote, instruct, teach, contribute to, and/or induce the use of such Biomet hip implants that embody the elements of at least claims 34 and/or 43 of the '852 patent; and Defendants did design, and do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or instruct medical professionals in the use of instruments and products that are specially designed for use in implanting Biomet hip implants, such as the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision

Acetabular Shells, that embody the elements of at least claims 34 and/or 43 of the '852 patent.

patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '852 patent as a result of the medical professionals use of Biomet hip implants and products, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the elements of at least claims 34 and/or 43 of the '852 patent, and were willfully blind as to their creation and/or distribution of instructions and surgical technique guides, such as the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, that encourage, promote, instruct, teach, disclose and set forth techniques for implanting such Biomet hip implants that embody the elements of at least claims 34 and/or 43 of the '852 patent.

- 234. Defendants' infringement of the '852 patent is and has been willful and deliberate.
- 235. Defendants knew of the '852 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT FIFTEEN (15): INFRINGEMENT OF THE '690 PATENT

- 236. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
 - 237. Defendants have and had actual and/or constructive knowledge of the '690 patent.
- 238. Defendants, directly or through the actions of their employees, divisions and/or subsidiaries, have infringed and continue to infringe the '690 patent, directly, indirectly, literally and/or equivalently.
- 239. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells that embody the elements of at least claims 23, 31 and/or 33 of the '690 patent. Defendants, among other things, make, use, offer for sale, sell, distribute, and/or import within the United States related instruments and products designed and specially adapted for medical professionals to implant and use the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells. Defendants, among other things, have created and/or distributed instructions for use and surgical technique guides, including, but not limited to, the

System technique guide, and have held, supported and sponsored courses for medical professionals that promote, teach, instruct, demonstrate, encourage, contribute to and induce the implantation and use of the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells that embody the elements of at least claims 23, 31 and/or 33 of the '690 patent. By these actions the Defendants, with actual and/or constructive knowledge of the '690 patent, have infringed and continue to infringe at least claims 23, 31 and/or 33 of the '690 patent, literally or equivalently.

- 240. Defendants have contributed to and continue to contribute to the infringement of the '690 patent by selling, offering to sell, supplying, and/or importing Biomet hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the elements of at least claims 23, 31 and/or 43 of the '690 patent. Defendants further contributed to and continue to contribute to the infringement of the '690 patent by designing, making, offering to sell, selling, supplying, distributing and/or importing into the United States instruments specially designed and adapted to implant and assist in the use of Biomet hip implants, such as the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, and further by creating and/or distributing surgical technique guides, such as the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, that promote, teach, instruct and encourage the use of such Biomet hip implants that embody the elements of at least claim 23, 31 and/or 33 of the '690 patent.
- 241. These Biomet hip implants, including but not limited to, the REGENEREXTM
 RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, are
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not staple articles or commodities of commerce suitable for substantial noninfringing use as they embody the elements of at least claims 23, 31 and/or 33 of the '690 patent.

- 242. Biomet hip implants, including, but not limited to, the REGENEREXTM
 RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells,
 and/or related instruments and products are a material part of the invention of the '690 patent for
 at least the reason that such hip implants, and/or the related instruments and products, are
 specially designed to assist in the use of such Biomet hip implants.
- 243. Defendants have induced and continue to induce the infringement of the '690 patent by: (1) selling, offering to sell, distributing, supplying, and/or importing Biomet hip implants, including, but not limited to, the REGENEREX™ RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, and/or related instruments and products, for use by medical professionals, (2) selling, offering to sell, distributing, supplying, and/or importing related instruments and products for use by medical professionals in using and implanting such Biomet hip implants, and (3) creating, distributing, and supplying medical professionals with Biomet surgical technique guides, including, but not limited to, the REGENEREX™ RINGLOC® + Modular Acetabular System surgical technique guide, that encourage, promote, instruct, teach and induce implantation of Biomet hip implants, such as the REGENEREX™ RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the elements of at least claims 23, 31 and/or 33 of the '690 patent.
- 244. With knowledge of the '690 patent and the specific intent to encourage, promote, instruct, teach, induce and/or contribute to the infringement of the '690 patent, Defendants did

encourage, promote, instruct, teach, contribute to, and/or induce medical professionals to use within the United States Biomet hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the elements of at least claims 23, 31 and/or 33 of the '690 patent, by: (1) creating, distributing, and/or supplying surgical technique guides and instructions for use, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, that encourage, promote, instruct, teach, contribute to and/or induce the use of such Biomet hip implants that embody the elements of at least claims 23, 31 and/or 33 of the '690 patent; and, (2) designing, manufacturing, offering for sale, selling, distributing, supplying, importing within the United States and/or instructing medical professionals in the use of hip implant related instruments for use with and for implanting such Biomet hip implants that embody the elements of at least claims 23, 31 and/or 43 of the '690 patent.

- 245. Medical professionals have infringed and continue to infringe the '690 patent, directly, indirectly, literally and by equivalents, by using in the United States Biomet hip implants, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the apparatus of at least claims 21, 31 and/or 33 of the '690 patent.
- 246. Defendants had and have actual and/or constructive knowledge of the infringement of the '690 patent by medical professionals, and knowingly induced and possessed specific intent to encourage such infringement, because with actual and/or constructive knowledge of the '690 patent, Defendants did make, offer to sell, sell, distribute, supply and/or import into the United States Biomet hip implants, including, but not limited to the

REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision

Acetabular Shells, that embody the elements of at least claims 23, 31 and/or 33 of the '690

patent; Defendants did create and/or distribute, and have created and/or distributed instructions

for use and surgical technique guides, the REGENEREXTM RINGLOC® + Modular Acetabular

System surgical technique guide, for such Biomet hip implants, that encourage, promote,

instruct, teach, contribute to, and/or induce the use of such Biomet hip implants that embody the

apparatus of at least claims 21, 31 and/or 33 of the '690 patent; and Defendants did design, and

do manufacture, offer for sale, sell, distribute, supply, import within the United States and/or

instruct medical professionals in the use of hip implant related instruments and products that are

specially designed for use in and are used in implanting Biomet hip implants, such as the

REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision

Acetabular Shells, that embody the elements of at least claims 21, 31 and/or 33 of the '690

patent.

247. At the very least, Defendants were willfully blind as to the existence of the '690 patent, and therefore willfully blinded themselves to medical professionals' direct infringement of the '690 patent as a result of the medical professionals use of Biomet hip implants and products, including, but not limited to, the REGENEREXTM RINGLOC® + Modular Acetabular System and REGENEREX Revision Acetabular Shells, that embody the elements of at least claims 23, 31 and/or 43 of the '690 patent, and were willfully blind as to their creation and/or distribution of instructions and surgical technique guides, such as the REGENEREXTM RINGLOC® + Modular Acetabular System surgical technique guide, that encourage, promote, instruct, teach, disclose and set forth techniques for implanting such Biomet hip implants that embody the elements of at least claims 21, 31 and/or 33 of the '690 patent.

- 248. Defendants' infringement of the '690 patent is and has been willful and deliberate.
- 249. Defendants knew of the '690 patent, Defendants ignored and/or disregarded that their actions constituted infringement of a valid patent, and Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent.

COUNT SIXTEEN (16): BREACH OF MARCTEC LICENSE AGREEMENT FOR FAILURE TO PAY ROYALTIES

- 250. Bonutti Skeletal realleges and incorporates by reference each of the preceding paragraphs.
- 251. On December 22, 2006, Arthrotek, Inc. (now known as BSM) entered the MarcTec License Agreement with MarcTec. Subsequently the MarcTec License Agreement was assigned from MarcTec to Bonutti Skeletal. The MarcTec License Agreement is a valid contract.
- 252. Under the MarcTec License Agreement BSM was granted a license to certain patents, which included the '073 patent. In exchange for the License, BSM was obligated to, inter alia, pay royalty fees on "Licensed Products."
- 253. Bonutti Skeletal, as Licensor, has performed its obligations under the MarcTec License Agreement.
- 254. The Defendants have materially breached the MarcTec License Agreement by failing to pay royalties on all Licensed Products, including, but not limited to, the ALLthread Knotless suture anchor. The ALLthread knotless suture anchor is covered by the '073 patent in

conjunction with its use as described in the Double Row Rotator Cuff Repair surgical technique guide as explained in Count Four (4), paragraphs 97-107, the allegations of which are incorporated by reference herein. Defendants have been on notice of its failure to pay royalties on the ALLthread Knotless suture anchor since at least January 2013.

255. Bonutti Skeletal has been and continues to be damaged by Defendants' failure to pay all royalties due under the MarcTec License Agreement.

DAMAGES AND RELIEF

- 256. As a consequence of Defendants' breach of the License Agreement, Bonutti Skeletal has been damaged in an amount not yet determined and will suffer additional irreparable damage unless Defendants' acts are enjoined by this Court.
- 257. The sales of implants made and sold by Defendants that either directly infringe or have been implanted using patented methods encouraged, promoted and induced by Defendants, as well as the sales of specially designed instruments made and sold by Defendants that either directly infringe or have been used to facilitate, assist in and induce the implantation of Defendants' implants using patented methods and techniques, as specifically set out in Counts 1 15, is an amount not yet determined, but is estimated, based upon published market data, to be in excess of \$3 billion for past infringing sales alone of these implants and instruments. Plaintiff intends to seek not less than a reasonable royalty for these past infringing sales of these implants and instruments.
- 258. As a consequence of Defendants' infringement of the patents-in-suit, Bonutti Skeletal has been damaged in an amount not yet determined and will suffer additional irreparable damage unless Defendants' infringing acts are enjoined by this Court.

PRAYER FOR RELIEF

- A. Determining that Defendants have breached and continue to breach the License Agreement;
- B. Determining that Defendants have infringed and continue to infringe one or more claims of the '986 patent;
- C. Determining that Defendants have infringed and continue to infringe one or more claims of the '531 patent;
- D. Determining that Defendants have infringed and continue to infringe one or more claims of the '063 patent;
- E. Determining that Defendants have infringed and continue to infringe one or more claims of the '279 patent;
- F. Determining that Defendants have infringed and continue to infringe one or more claims of the '821 patent;
- G. Determining that Defendants have infringed and continue to infringe one or more claims of the '557 patent;
- H. Determining that Defendants have infringed and continue to infringe one or more claims of the '073 patent;
- I. Determining that Defendants have infringed and continue to infringe one or more claims of the '996 patent;
- J. Determining that Defendants have infringed and continue to infringe one or more claims of the '740 patent;
- K. Determining that Defendants have infringed and continue to infringe one or more claims of the '896 patent;

- L. Determining that Defendants have infringed and continue to infringe one or more claims of the '897 patent;
- M. Determining that Defendants have infringed and continue to infringe one or more claims of the '852 patent;
- N. Determining that Defendants have infringed and continue to infringe one or more claims of the '690 patent;
- O. Determining that Defendants have infringed and continue to infringe one or more claims of the '229 patent;
- P. Determining that Defendants have infringed and continue to infringe one or more claims of the '514 patent;
- Q. Preliminarily and permanently enjoining Defendants, their respective officers, agents, servants, directors, employees and attorneys, and all persons acting in concert or participation with it, directly or indirectly, or any of them who receive actual notice of the judgment, from further infringing, inducing others to infringe, or contributing to the infringement of the patents-in-suit;
- R. Ordering Defendants to account for and pay to Bonutti Skeletal all damages suffered by Bonutti Skeletal as a consequence of Defendants' breach of the License Agreement, together with interest and costs as fixed by the Court;
- S. Ordering Defendants to account for and pay to Bonutti Skeletal all damages suffered by Bonutti Skeletal as a consequence of Defendants' infringement of the patents-in-suit, together with interest and costs as fixed by the Court;
- T. Trebling or otherwise increasing Bonutti Skeletal's damages under U.S.C. § 284 on the grounds that Defendants' infringement of the patents-in-suit was deliberate and willful;

- U. Declaring that this case is exceptional and awarding Bonutti Skeletal its costs and attorneys' fees in accordance with 35 U.S.C. § 285; and
- V. Granting Bonutti Skeletal such other and further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Bonutti Skeletal hereby requests a trial by jury for all issues so triable.

Dated May 31, 2013 Respectfully submitted,

By: /s/ Brian M. Rothery

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Counsel for: Plaintiff Bonutti Skeletal Innovations LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 31, 2013, I electronically filed a true and correct copy of the foregoing document with the Clerk of the Court for the Eastern District of Texas by using the CM/ECF system, which will send notice of filing to all counsel of record.

s/Leslie S. Kramer Leslie S. Kramer