

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RSB SPINE, LLC,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
PRECISION SPINE, INC.,) **JURY TRIAL DEMANDED**
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff RSB Spine, LLC (“RSB” or “Plaintiff”) hereby asserts claims against Precision Spine, Inc. (“Precision” or “Defendant”) for infringement of U.S. Patent Nos. 6,235,034 (“the ’034 Patent”), 6,984,234 (“the ’234 Patent”), and 9,713,537 (“the ’537 Patent”) and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

THE PARTIES

2. RSB is a limited liability company organized and existing under the laws of Delaware with its principal place of business at 2530 Superior Avenue # 703, Cleveland, OH 44114.

3. Upon information and belief, Precision is a corporation organized and existing under the laws of Delaware with its place of business at 5 Sylvan Way, 2nd Floor, Parsippany, NJ 07054.

4. Upon information and belief, Precision manufactures and distributes spinal pathology solutions, including anterior lumbar interbody fusion (ALIF) devices.

5. Upon information and belief, Precision sells and offers to sell products and services throughout the United States, including in this judicial district, and introduces products and services into the stream of commerce and that incorporate infringing technology knowing that they would be sold in this judicial district and elsewhere in the United States.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code.

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this judicial district under 28 U.S.C. § 1400(b).

9. Precision is subject to this Court's general and specific personal jurisdiction because it is incorporated in Delaware and has purposely availed itself of the privileges and benefits of the laws of the State of Delaware. Further, upon information and belief, Precision has sufficient minimum contacts within the State of Delaware because Precision purposefully availed itself of the privileges of conducting business in the State of Delaware, Precision regularly conducts and solicits business within the State of Delaware, and RSB's causes of action arise directly from Precision's business contacts and other activities in the State of Delaware.

BACKGROUND

RSB and Its Spinal Stabilization Devices

10. RSB Spine, LLC, was formed in 2001 as R&B Surgical Solutions ("R&B") by John A. Redmond and Robert S. Bray, Jr., M.D. to develop and market spinal implant concepts from Dr. Bray and other innovative spine surgeons.

11. Dr. Bray, the sole inventor or co-inventor on all asserted patents, is currently the Director of St. Johns Spine Institute in Santa Monica, California, was the Founding Director of

The Institute for Spinal Disorders for Cedars Sinai, and the founder of a Multidisciplinary Outpatient Center, D.I.S.C. (Diagnostic and Interventional Spinal Care).

12. Dr. Bray was a Major in the United States Air Force and served as the Chief of Neurosurgery at Travis Air Force Base. Dr. Bray has been awarded eight U.S. patents for spinal implants and neurosurgical instruments, with several more applications pending, and has performed more than 7,500 spinal surgeries, including using devices covered by the asserted patents.

13. R&B's strategy was to use its instrument line to generate revenue and build distribution while the novel implants were being developed. In 2003, R&B sold its instrument line. The company then changed its name to RSB Spine, LLC.

14. Proceeds of the sale provided the requisite capital to launch the company's first implant system.

15. In August 2006, the FDA approved RSB's InterPlate™ product, as a vertebral body replacement. The InterPlate™ product is a platform technology for performing fusion procedures in the lumbar and cervical spine. The InterPlate™ implants, made from both titanium and polyetheretherketone (PEEK), offer surgeons a very unique and different option as compared with existing plates and interbody devices.

16. In July 2007, the FDA reclassified interbody fusion devices and as of September 18, 2007 the InterPlate™ became the first device cleared for interbody fusion under the new guidelines.

17. The current InterPlate™, sold for use in the cervical and lumbar spine, is made of titanium and is used in conjunction with graft material for fusion of adjacent vertebral bodies.

18. RSB's products are exclusively distributed by Paradigm BioDevices in the United States.

19. RSB and Paradigm BioDevices provide public notice in compliance with 35 U.S.C. § 287 that the InterPlate™ products incorporate the inventions of, among others, U.S. Patent Nos. 6,235,034, 6,984,234, and 9,713,537 (the “Asserted Patents”). The product packaging, product inserts and RSB’s website identify RSB’s patents, including the Asserted Patents.

RSB Patents

20. The spinal column of vertebrates provides support to bear weight and protection to the delicate spinal cord and spinal nerves. The spinal column comprises a series of vertebrae stacked on top of each other. There are typically seven cervical (neck), twelve thoracic (chest), and five lumbar (low back) segments. Each vertebra has a cylindrical shaped vertebral body in the anterior portion of the spine with an arch of bone to the posterior which covers the neural structures. Between each vertebral body is an intervertebral disk, a cartilaginous cushion to help absorb impact and dampen compressive forces on the spine. To the posterior, the laminar arch covers the neural structures of the spinal cord and nerves for protection. At the junction of the arch and anterior vertebral body are articulations to allow movement of the spine.

21. Various types of problems can affect the structure and function of the spinal column. These can be based on degenerative conditions of the intervertebral disk or the articulating joints, traumatic disruption of the disk, bone or ligaments supporting the spine, tumor or infection. In addition congenital or acquired deformities can cause abnormal angulation or slippage of the spine. Slippage (spondylolisthesis) anterior of one vertebral body on another can cause compression of the spinal cord or nerves. Patients who suffer from one of more of these

conditions often experience extreme and debilitating pain, and can sustain permanent neurologic damage if the conditions are not treated appropriately.

22. One technique of treating these disorders is known as surgical arthrodesis of the spine. This can be accomplished by removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral bodies together. The stabilization of the vertebra to allow fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone. Such techniques have been effectively used to treat the above described conditions and in most cases are effective at reducing the patient's pain and preventing neurologic loss of function. However, there are disadvantages to these stabilization devices.

23. The inventions of the Asserted Patents relate to medical stabilization devices, used to repair or alleviate these types of injuries to the spine.

24. Dr. Bray's inventions overcame disadvantages of prior stabilization devices, systems and methods as well as the tools then available to implant them. The disadvantages of prior art stabilization devices included the inability to properly affix the device to the spine and the inability for the device to properly bear the weight of adjacent vertebral bodies.

The '034 Patent

25. RSB is the assignee and owner of the right title and interest in and to the '034 Patent having acquired those rights on September 8, 2008, including the right to assert all causes of action arising under the '034 Patent and the right to any remedies for infringement, including remedies for past infringements.

26. The '034 Patent, entitled "Bone Plate and Bone Screw Guide Mechanism," was issued by the United States Patent and Trademark Office on May 22, 2001. The '034 Patent issued from United States Patent Application No. 09/177,885, filed on October 23, 1998, and claims priority to United States Provisional Application No. 60/063,035, filed on October 24, 1997. A copy of the '034 Patent is attached as **Exhibit A**.

27. The inventions of the '034 Patent are generally directed to a bone plate for assisting with the surgical arthrodesis (fusion) of two or more bones together, and a bone screw guide mechanism to assist in the proper drilling, tapping and placement of the bone screws to secure the plate.

28. The '034 Patent is valid, enforceable and duly issued in full compliance with Title 35 of the United States Code.

The '234 Patent

29. RSB is the assignee and owner of the right title and interest in and to the '234 Patent having acquired those rights on October 10, 2005, including the right to assert all causes of action arising under the '234 Patent and the right to any remedies for infringement, including remedies for past infringements.

30. The '234 Patent, entitled "Bone Plate Stabilization System and Method for its Use," was issued by the United States and Patent Trademark Office on January 10, 2006. The '234 Patent issued from United States Patent Application No. 10/419,652, filed on April 21, 2003. A copy of the '234 Patent is attached as **Exhibit B**.

31. The inventions of the '234 Patent are generally directed to a bone plate system that is particularly useful for assisting with the surgical arthrodesis (fusion) of two bones

together, and more particularly, to a bone plate that provides and controls limited movement between the bones during fusion.

32. The '234 Patent is valid, enforceable and duly issued in full compliance with Title 35 of the United States Code.

The '537 Patent

33. RSB is the assignee and owner of the right title and interest in and to the '537 Patent having acquired those rights on January 23, 2017, including the right to assert all causes of action arising under the '537 Patent and the right to any remedies for infringement, including remedies for past infringements.

34. The '537 Patent, entitled "Bone Plate Stabilization System and Method For Its Use," was issued by the United States and Patent Trademark Office on July 25, 2017. The '537 Patent issued from United States Patent Application No. 15/413,945, filed on January 24, 2017 and claims priority through a series of continuing applications to the filing date of the '234 Patent, April 21, 2003. A copy of the '537 Patent is attached as **Exhibit C**.

35. The '537 Patent is valid, enforceable and duly issued in full compliance with Title 35 of the United States Code.

Precision's Knowledge of Patent Infringement

36. On July 5, 2018, RSB sent a notice letter to Precision including examples of Precision's patent infringement. RSB further indicated its willingness to engage in meaningful licensing discussions.

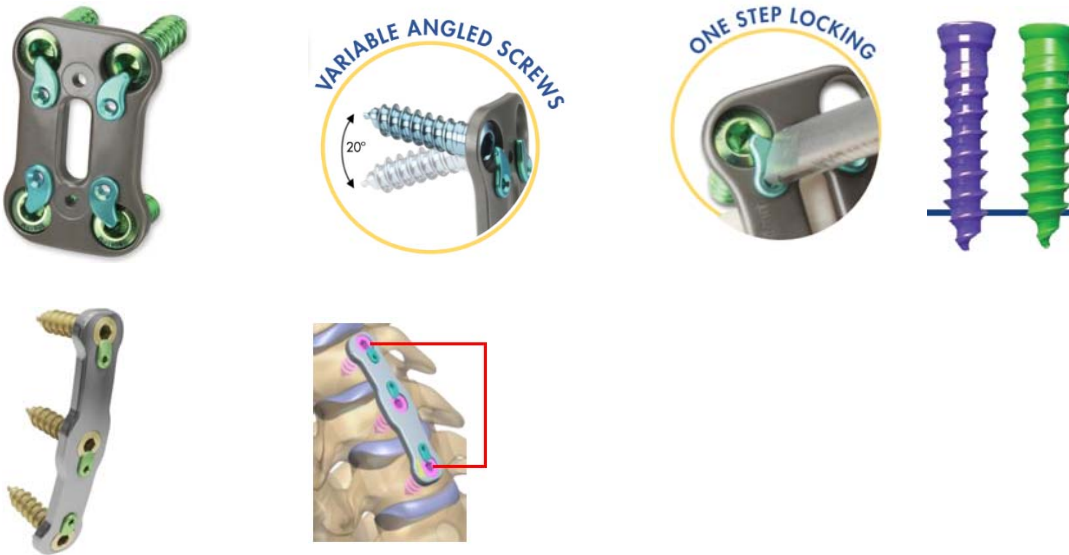
37. RSB identified at least the Vault® C Anterior Cervical Discectomy and Fusion System (ACDF), and Vault® ALIFP System as infringing the '537 Patent and at least the

Precision Slimplicity® Anterior Cervical Plating System and the AccuFit® ALIF Plate System as infringing the '034 Patent.

38. RSB requested a response to its notice to Precision within a reasonable period, but Precision has yet to provide any response.

The Accused Products

39. Precision's Slimplicity® Anterior Cervical Plating System and Slimplicity® Solo Anterior Cervical Plate System are illustrated below.



40. The Slimplicity® Anterior Cervical Plate System is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; spinal stenosis; pseudoarthrosis; and failed previous fusions.

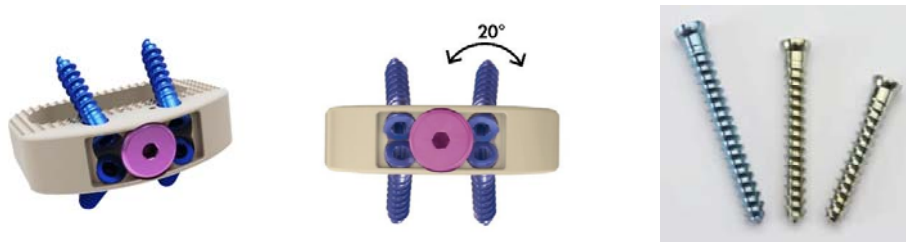
41. The Slimplicity® Solo Anterior Cervical Plate System is intended for anterior cervical fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

42. Precision's AccuFit® ALIF Plate System and the AccuFit Lateral Plate System are illustrated below.



43. The AccuFit® ALIF Plate System is a lumbosacral fixation system offering two low-profile plate designs to facilitate anatomical fit and protect surrounding vascular structures. The AccuFit Plate features an intuitive one step locking system that provides visual locking confirmation and a large graft window for extensive visibility to the endplates, as well as the interbody spacer. Fixed and variable screws in 5.0 and 5.5 mm sizes are offered to accommodate surgical preferences. The AccuFit® Lateral Plate System is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L 5) spine instability. The AccuFit® Lateral Plate System consists of non-sterile, single use, titanium alloy (Ti-6Al-4V ELI per ASTM F136) rigid plates and bone screws of varying sizes and lengths. The plate attaches by means of screws to the lateral portion of the vertebral body of the thoracolumbar spine (T1-L5).

44. Precision's Vault® ALIF System is illustrated below.



45. The Vault® ALIF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The Vault® Stand-Alone ALIF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device. The Vault® Stand-Alone ALIF System is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixations.

46. Precision's Vault® C ACDF System is illustrated below.



47. The Vault® C ACDF System implants are available in various heights and geometric footprints to accommodate individual patient anatomy and graft material size. Vault® C Interbody devices are inserted through an anterior cervical approach and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance, while screws are inserted through the anterior titanium portion of the implant for bone fixation.

The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

48. The Vault® C Anterior Cervical Discectomy and Fusion System (ACDF) and Vault® ALIF System are referred to herein as “the Accused Vault Products”. The Precision Slimplicity® Anterior Cervical Plating System, the Precision Slimplicity® Solo Anterior Cervical Plate System, the AccuFit® ALIF Plate System, and the AccuFit® Lateral Plate System are referred to herein as the “Accused Plate Products”. Collectively, the Accused Vault Products and Accused Plate Products are referred to herein as “the Accused Products”.

COUNT I – INFRINGEMENT OF U.S. PATENT 6,235,034

49. RSB realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 48 of the Complaint as though fully set forth herein.

50. Upon information and belief, Precision has directly and indirectly infringed, literally and under the doctrine of equivalents, at least claim 1 of the '034 Patent by making, using, selling, and/or offering for sale the Accused Products.

51. Claim 1 of the '034 Patent claims a novel bone plate with the following limitations:

a base plate having at least two screw holes;

at least two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone, wherein the bone screws have heads shaped to toggle within the screw holes; and

a bone screw locking means capable of securedly covering the bone screws so that the bone screws cannot back out from the bone once screwed in through the base plate;

wherein the bone screws and bone screw locking means are designed such that when the bone screw locking means covers the bone screws and is fixedly attached to said base plate, the top of

each bone screw mates with the bone screw locking means and each bone screw can toggle within its corresponding screw hole.

52. The Accused Products contain each of the above limitations. *See, e.g., Exhibit D.*

53. The Accused Products have a base plate, at least two screw holes, and at least two bone screws.

54. The bone screws are used to secure the bone plate to a bone by insertion through the screw holes into the bone. The bone screws also have heads shaped to toggle within the screw holes.

55. The base plates of the Accused Products have a bone screw locking means that securedly covers the bone screws so that the bone screws cannot back out from the bone once screwed in through the base plate.

56. When the bone screw locking means of the Accused Products cover the associated bone screws and fixedly attach to the base plate of the Accused Products, the top of each bone screw mates with the bone screw locking means, and each bone screw can toggle within its corresponding screw hole.

57. Upon information and belief, Precision marketed and sold the Accused Products in the United States to its partners, clients, customers, and end users who use the Accused Products across the country and in this District.

58. Upon information and belief, since at least July 5, 2018, Precision had knowledge of the '034 Patent and has induced others to infringe at least one claim of the '034 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Precision's partners,

clients, customers, and end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the '034 Patent.

59. In particular, Precision's actions that aid and abet others such as its partners, clients, customers and end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

60. Upon information and belief, Precision is liable for contributory infringement of the '034 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States Accused Products to be especially made or adapted for use to infringe the '034 Patent. The Accused Products are a material component for use in practicing the '034 Patent, are specifically made, and are not a staple article of commerce suitable for substantial non-infringing use.

61. As a consequence of each of Precision's direct and indirect infringement, both literal and under the doctrine of equivalents, of the '034 Patent, RSB has been damaged in an amount not yet determined and is entitled to recover damages pursuant to 35 U.S.C. § 284.

62. Upon information and belief, Precision's infringement of the '034 Patent has been willful. Precision knew of the '034 Patent and knew that it was infringing the '034 Patent at least as early as July 5, 2018. Despite RSB's indication to Precision that RSB was willing to engage in meaningful licensing discussions, Precision did not respond, choosing instead to continue infringing in willful disregard of RSB's patent rights.

COUNT II – INFRINGEMENT OF U.S. PATENT 6,984,234

63. RSB realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 62 of the Complaint as though fully set forth herein.

64. Upon information and belief, Precision has infringed and continues to infringe directly and indirectly, literally and under the doctrine of equivalents, at least claims 1, 22, and 35 of the '234 Patent by making, using, selling, and/or offering for sale the Accused Vault Products.

65. Claim 1 of the '234 Patent claims a novel method for joining first and second bones with the following limitations:

inserting between the side surfaces of the bones a base plate having a first end nearer the first bone and a second end nearer the second bone, wherein the base plate has a first screw hole extending through the first end and a second screw hole extending through the second end;

introducing a first bone screw through the first screw hole and into the first bone, wherein the first bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 60°,

introducing a second bone screw through the second screw hole and into the second bone, wherein the second bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 70°, and

covering at least a part of the first bone screw and at least a part of the second bone screw to prevent the first and second bone screws from backing out of the first and second bones, respectively.

66. The use of the Accused Vault Products meets each of the above limitations. *See, e.g., Exhibit E.*

67. The Accused Vault Products are used to join adjacent bones having top surfaces and side surfaces generally facing each other.

68. The Accused Vault Products include a base plate that is inserted between the side surfaces of the adjacent bones. The base plate has a first end nearer the first bone and a second

end nearer the second bone. The base plate has a first screw hole extending through the first end and a second screw hole extending through the second end.

69. To secure the Accused Vault Products, a first bone screw is inserted through the first screw hole and into the first bone and a second bone screw is inserted through the second screw hole and into the second bone, at an angle relative to the top surface of the bone between 20 and 60 degrees and between 20 and 70 degrees, respectively.

70. Part of the first bone screw and part of the second bone screw are covered to prevent the bone screws from backing out of the bones.

71. Claim 22 of the '234 Patent claims a novel bone stabilization plate system with the following limitations:

a base plate having bottom surface and first and second ends, the first end comprising a first bone screw region having a first bone screw hole extending therethrough at an angle relative to the bottom surface of the base plate ranging from about 20° to about 60°, and the second end comprising a second bone screw region having a second bone screw hole extending therethrough at an angle relative to the bottom surface of the base plate ranging from about 20° to about 70°;

a first bone screw capable of securing the base plate to a first bone by insertion through the first bone screw hole;

a second bone screw capable of securing the base plate to a second bone by insertion through the second bone screw hole; and

a bone screw retaining means for securedly covering at least a part of the first and second bone screws to prevent the bone screws from backing out from the first and second bones.

72. The Accused Vault Products contain each of the above limitations. *See, e.g.,*

Exhibit E.

73. The Accused Vault Products include a base plate having first and second ends and respective bone screw regions including bone screw holes extending therethrough. A first bone

screw hole extends at an angle of 20 to 60 degrees relative to the bottom surface of the base plate and a second bone screw hole extends at an angle from 20 to 70 degrees relative to the bottom surface of the base plate.

74. The Accused Vault Products include first and second bone screws capable of securing the base plate to the first and second bones, respectively.

75. The Accused Vault Products include bone screw retaining means for securedly covering at least part of the first and second bone screws to prevent the bone screws from backing out of the first and second bones.

76. Claim 35 of the '234 Patent claims a novel bone stabilization plate system with the following limitations:

a base plate for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies and for permitting force transmission between the first and second bone bodies through the bone graft material,

the base plate being sized to have an inter-fit between the first and second adjacent bone bodies and adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material, and

at least first and second bone screws for extending into the first and second bone bodies, respectively, to retain the base plate between the first and second bone bodies,

the base plate having means for interacting with the first and second bone screws, the means for interacting including means for permitting movement of at least one of the first and second bone bodies relative to the base plate.

77. The Accused Vault Products contain each of the above limitations. *See, e.g.,*

Exhibit E.

78. The Accused Vault Products include a base plate for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies and for permitting force transmission between the first and second bone bodies through the bone graft material.

79. The base plate is sized to have an inter-fit between the first and second adjacent bone bodies and adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material.

80. The Accused Vault Products have first and second bone screws for extending into the first and second bone bodies.

81. The base plate has a means for permitting movement of at least one of the first and second bone bodies relative to the base plate.

82. Upon information and belief, Precision markets and sells the Accused Vault Products in the United States to its partners, clients, customers, and end users who use the Accused Vault Products across the country and in this District.

83. Upon information and belief, at least since receiving notice of infringement, Precision has induced and continues to induce others to infringe at least one claim of the '234 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Precision's partners, clients, customers, and end users, whose use of the Accused Vault Products constitutes direct infringement of at least one claim of the '234 Patent.

84. In particular, Precision's actions that aid and abet others such as its partners, clients, customers and end users to infringe include advertising and distributing the Accused Vault Products and providing instruction materials, training, and services regarding the Accused Vault Products.

85. Upon information and belief, Precision is liable for contributory infringement of the '234 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States Accused Vault Products to be especially made or adapted for use to infringe the '234 Patent. The Accused Vault Products are a material component for use in practicing the '234 Patent and are specifically made and are not a staple article of commerce suitable for substantial non-infringing use.

86. As a consequence of each of Precision's direct and indirect infringement, both literal and under the doctrine of equivalents, of the '234 Patent, RSB has been, and continues to be, damaged in an amount not yet determined and is entitled to recover damages pursuant to 35 U.S.C. § 284.

87. Upon information and belief, Precision's infringement of the '234 Patent will continue in the future, and RSB will continue to suffer damages, as a consequence, unless Precision's infringing acts are enjoined by this Court.

88. Upon information and belief, Precision's infringement of the '234 Patent has been, and continues to be, willful. Precision knew of the '234 Patent and knew that it was infringing the '234 Patent. Despite RSB's indication to Precision that RSB was willing to engage in meaningful licensing discussions, Precision has not responded; choosing instead to continue infringing in willful disregard of RSB's patent rights.

COUNT III – INFRINGEMENT OF U.S. PATENT 9,713,537

89. RSB realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 88 of the Complaint as though fully set forth herein.

90. Upon information and belief, Precision has infringed and continues to infringe directly and indirectly, literally and under the doctrine of equivalents, at least claims 1, 15, and

21 of the '537 Patent by making, using, selling, and/or offering for sale the Accused Vault Products.

91. Claim 1 of the '537 Patent claims a novel bone stabilization system with the following limitations:

a base plate having a top surface, first and second ends, a bottom surface, and a plurality of bone screw holes, wherein the base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion; and

a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively;

wherein the vertebral bones have top surfaces and have side surfaces generally facing each other;

wherein a first of the bone screw holes, being configured to receive a first of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the side surface of a first of the vertebral bones;

wherein a second of the bone screw holes, being configured to receive a second of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the lip osteophyte of a second of the vertebral bones; and

wherein each and every one of the plurality of bone screw holes is configured to receive one of the bone screws angled relative to the base plate and oriented generally in an anterior-posterior direction through at least partially the top surface of the base plate.

92. The Accused Vault Products contain each of the above limitations. *See, e.g.,*

Exhibit F.

93. The Accused Vault Products are each bone stabilization systems with base plates having a top surface, a bottom surface and more than one bone screw hole.

94. The Accused Vault Products further include base plates configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion.

95. The Accused Vault Products have multiple bone screws configured to fit in multiple bone screw holes. The vertebral bones have top surfaces and have side surfaces generally facing each other.

96. The Accused Vault Products have a first of the bone screw holes configured to receive a first of the bone screws that extends at least partially from the top surface of a base plate and opens at least partially toward the side surface of a first of the vertebral bones.

97. The Accused Vault Products also have a second of the bone screw holes configured to receive a second of the bone screws that extends at least partially from the top surface of a base plate and opens at least partially toward the lip osteophyte of a second of the vertebral bones.

98. The Accused Vault Products have bone screw holes configured to receive one of the bone screws angled relative to a base plate and oriented generally in an anterior-posterior direction through at least partially the top surface of the base plate.

99. Claim 15 of the '537 Patent claims a novel bone stabilization plate system with the following limitations:

a base plate having a plurality of bone screw holes, a top surface, a generally flat bottom surface and first and second ends for retaining bone graft material between adjacent vertebral bone bodies having top surfaces and having side surfaces generally facing each other,

wherein the base plate is configured to fit primarily between anterior portions of the bone bodies' lip osteophytes, without covering significant portions of the top surfaces of the bone bodies, to primarily bear weight, and to permit force transmission between

the bone bodies through the bone graft material while holding the bone bodies for fusion; and

a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into the lip osteophytes, with each of the bone screws being configured to extend from at least partially the top surface of the base plate to at least partially the side surface of one of the bone bodies, such that the base plate is secured.

100. The Accused Vault Products contain each of the above limitations. *See, e.g.,*

Exhibit F.

101. The Accused Vault Products include a base plate having a plurality of bone screw holes and retain bone graft material between adjacent vertebral bone bodies. The base plate fits between anterior portions of the bone bodies' lip osteophytes without covering significant portions of the top surfaces of the bone bodies.

102. The base plate bears weight and permits force transmission between the bone bodies through the bone graft material while holding the bone bodies for fusion.

103. The Accused Vault Products include a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into the lip osteophytes, with each of the bone screws being configured to extend from at least partially the top surface of the base plate to at least partially the side surface of one of the bone bodies, such that the base plate is secured.

104. Claim 21 of the '537 Patent claims a novel bone stabilization plate system for anchoring between side surfaces of first and second adjacent vertebral bones with the following limitations:

a base plate having a top surface, a first end nearer the first bone comprising a first bone screw hole extending at least partially therethrough and a first bone engaging region fully extending uninterrupted between lateral extents of the first end, a second end

nearer the second bone comprising a second bone screw hole extending at least partially therethrough, and a bottom surface, and configured to fit primarily between an anterior portion of the first bone's lip osteophyte and an anterior portion of the second bone's lip osteophyte while bearing weight to hold the bones for fusion; and

a first bone screw configured to secure the base plate to the first bone by insertion through the first bone screw hole and to extend from at least partially the top surface of the base plate to at least partially the side surface of the first bone, and a second bone screw configured to secure the base plate to the second bone by insertion through the second bone screw hole and to extend from at least partially the top surface of the base plate to at least partially the side surface of the second bone.

105. The Accused Vault Products contain each of the above limitations. *See, e.g.,*

Exhibit F.

106. The Accused Vault Products anchor between side surfaces of a first and second adjacent vertebral bone.

107. The Accused Vault Products are designed to include a base plate having a top surface, a first end nearer to the first bone with a first bone screw hole extending at least partially therethrough and a first bone engaging region fully extending uninterrupted between lateral extents of the first end and, a second end nearer the second bone with a second bone screw hole extending at least partially therethrough, and a bottom surface.

108. The base plate of the Accused Vault Products is also configured to fit primarily between an anterior portion of a first bone's lip osteophyte and an anterior portion of a second bone's lip osteophyte while bearing weight to hold bones for fusion.

109. The first bone screw is configured to secure the base plate to the first bone by insertion through the first bone screw hole and to extend from the top surface of the base plate to the side surface of the first bone.

110. The second bone screw is configured to secure the base plate to the second bone by insertion through the second bone screw hole and to extend from the top surface of the base plate to the side surface of the second bone.

111. Upon information and belief, Precision markets and sells the Accused Vault Products in the United States to its partners, clients, customers, and end users who use the Accused Vault Products across the country and in this District.

112. Upon information and belief, since at least July 5, 2018, Precision has induced and continues to induce others to infringe at least one claim of the '537 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Precision's partners, clients, customers, and end users, whose use of the Accused Vault Products constitutes direct infringement of at least one claim of the '537 Patent.

113. In particular, Precision's actions that aid and abet others such as its partners, clients, customers and end users to infringe include advertising and distributing the Accused Vault Products and providing instruction materials, training, and services regarding the Accused Vault Products.

114. Upon information and belief, Precision has engaged in such actions with specific intent to cause infringement or with willful blindness to the resulting infringement, because Precision has had actual knowledge of the '537 Patent and knowledge that its acts were inducing infringement of the '537 Patent since at least July 5, 2018.

115. Upon information and belief, Precision is liable for contributory infringement of the '537 Patent under 35 U.S.C. § 271(c) by offering to sell and selling in the United States Accused Vault Products to be especially made or adapted for to infringe the '537 Patent. The

Accused Vault Products are a material component for use in practicing the '537 Patent and are specifically made and are not a staple article of commerce suitable for substantial non-infringing use.

116. As a consequence of each of Precision's direct and indirect infringement, both literal and under the doctrine of equivalents, of the '537 Patent, RSB has been, and continues to be, damaged in an amount not yet determined and is entitled to recover damages pursuant to 35 U.S.C. § 284.

117. Upon information and belief, Precision's infringement of the '537 Patent will continue in the future, and RSB will continue to suffer damages, as a consequence, unless Precision's infringing acts are enjoined by this Court.

118. Upon information and belief, Precision's infringement of the '537 Patent has been, and continues to be, willful. Precision knew of the '537 Patent and knew that it was infringing the '537 Patent at least as early as July 5, 2018. Despite RSB's indication to Precision that RSB was willing to engage in meaningful licensing discussions, Precision has not responded; choosing instead to continue infringing in willful disregard of RSB's patent rights.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, RSB demands a trial by jury on all triable issues.

PRAYER FOR RELIEF

WHEREFORE, if RSB is unsuccessful securing a reasonable royalty prior to service of this Complaint, RSB demands judgment for itself and against Precision as follows:

- A. An adjudication that Precision has infringed the Asserted Patents;

B. A permanent injunction against Precision, its officers, agents, servants, employees, attorneys, parent and subsidiary corporations, assigns and successors in interest, and those persons in active concert or participation with them, enjoining them from continued acts of infringement of the '234 Patent and the '537 Patent;

C. An award of damages to be paid by Precision adequate to compensate RSB for Precision's past infringement of the Asserted Patents, and any continuing or future infringement of the '234 Patent and '537 Patent through the date such judgment is entered, including pre-judgment and post-judgment interest, costs, expenses and an accounting of all infringing acts including, but not limited to, those acts presented at trial as well as those acts not presented at trial;

D. An adjudication that Precision's infringement has been willful and an award of treble damages;

E. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of RSB's reasonable attorneys' fees; and

F. An award to RSB of such further relief at law or in equity as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

OF COUNSEL:

Erik B. Milch
Frank V. Pietrantonio
Dustin M. Knight
COOLEY LLP
11951 Freedom Drive
One Freedom Square
Reston, VA 20190-5656
(703) 456-8000

Christopher C. Campbell
Rose S. Whelan
COOLEY LLP
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004
(202) 842-7800

Joseph M. Drayton
COOLEY LLP
1114 Avenue of the Americas, 46th Floor
New York, NY 10036-7798
(212) 479-6000

December 13, 2018

Jack B. Blumenfeld (#1014)
Michael J. Flynn (#5333)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mflynn@mnat.com

Attorneys for Plaintiff