

Mark O. Morris (4636)
SNELL & WILMER L.L.P.
15 West South Temple, Suite 1200
Salt Lake City, Utah 84101
Telephone: (801) 257-1900
Facsimile: (801) 257-1800
Email: mmorris@swlaw.com

Erik B. Milch (pro hac vice application anticipated)
Elizabeth Shrieves (pro hac vice application anticipated)
Sarah W. Ghivizzani (pro hac vice application anticipated)
PROSKAUER ROSE LLP
1001 Pennsylvania Ave., NW
Suite 600 South
Washington, DC 20004-2533
(202) 416-6899

Baldassare Vinti (pro hac vice application anticipated)
Joseph M. Drayton (pro hac vice application anticipated)
Connor J. Villar (pro hac vice application anticipated)
PROSKAUER ROSE LLP
Eleven Times Square
New York, NY 10036-8299
(212) 969-2900

Attorneys for Plaintiff

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH**

RSB SPINE, LLC,)
)
Plaintiff,)
)
v.)
)
INNOVASIS, INC.,)
)
Defendant.)

**COMPLAINT FOR PATENT
INFRINGEMENT**
JURY TRIAL DEMANDED

Case No. 2:24-cv-00264-DBB

Judge: David Barlow
Magistrate Judge:

Plaintiff RSB Spine, LLC (“RSB” or “Plaintiff”) hereby asserts claims against Innovasis, Inc. (“Innovasis” or “Defendant”) for infringement of U.S. Patent No. 9,713,537 (the “’537 Patent” or the “Asserted 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 1877 Eagle Pass, Wooster, Ohio 44691.

3. Upon information and belief, Innovasis is a corporation organized and existing under the laws of Utah with its place of business at 614 E 3900 S, Salt Lake City, Utah 84107.

4. Upon information and belief, Innovasis manufactures and distributes spinal therapy products, including anterior lumbar interbody fusion (ALIF) devices.

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

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 on the Asserted Patent, is the CEO and founding director of DISC Sports & Spine Center, was 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 founded 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 sixteen U.S. patents for spinal implants and neurosurgical instruments, with several more applications pending, and has performed more than 14,000 spinal surgeries, including using devices covered by the asserted patents.

13. R&B's strategy was to use the instrument line to generate revenue and build distribution while the novel implants were being developed. In 2003, R&B sold its instrument line. As a condition of sale, the company 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 invention of, among others, U.S. Patent Nos. 6,984,234; 9,713,537 (the '537 Patent); and 11,026,802. The product packaging, product inserts, and RSB's website identify RSB's patents, including the Asserted Patent.

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 for treating these disorders is known as surgical arthrodesis of the spine. This can be accomplished by removing the intervertebral disk, 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 invention of the '537 Patent relates 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, among other things, 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 '537 Patent

25. RSB is the assignee and owner of the right of 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 infringement.

26. 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 was issued on United States Patent Application No. 15/413,945 and filed on January 24, 2017. A copy of the '537 Patent is attached as **Exhibit A**.

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

28. In fact, RSB has previously enforced the '537 Patent against infringers. In 2018, RSB filed complaints against Xtant Medical Holdings, Inc., Precision Spine, Inc., Medacta USA, Inc., and Life Spine, Inc. in the District of Delaware asserting patent infringement of the '537 Patent. *See* Case Nos. 1:18-cv-01976, 1:18-cv-01974, 1:18-cv-01973, 1:18-cv-01972. Those defendants ultimately all chose to license the '537 Patent.

29. In 2019, RSB enforced the '537 Patent against DePuy Synthes Sales, Inc., DePuy Synthes Sales, Inc., and DePuy Synthes Inc., also in the District of Delaware. The case proceeded to trial in 2022, where RSB was awarded a \$12 million jury verdict for DePuy's infringement of the '537 patent. *See Exhibit B*. The jury also determined that the '537 Patent was not shown to be invalid. *Id.*

30. Just recently, in October 2023, RSB enforced the '537 Patent against Orthofix Medical, Inc., SeaSpine Holdings Corp., SeaSpine, Inc., and SeaSpine Orthopedics Corp. in the Eastern District of Texas. *See RSB Spine, LLC v. Orthofix Medical, Inc.*, No. 4:23-cv-00959 (E.D. Tex.). After a settlement, a stipulation of dismissal was filed in that case on February 12, 2024.

31. The validity of the '537 Patent was also upheld by the Patent Trial and Appeal Board. In 2019, Medacta USA, Inc., Precision Spine, Inc., and Life Spine, LLC filed two *inter partes* review petitions challenging the validity of the '537 Patent. *See* PTAB-IPR2020-00264; PTAB-IPR-2020-00275. The Patent Trial and Appeal Board denied institution of one petition outright and reached a final decision on the other petition, determining that all claims of the '537 Patent were not unpatentable. *See Exhibits C and D*.

32. In addition to the parties who have licensed the '537 Patent as a result of litigation, three additional parties licensed the '537 Patent outside of litigation.

Innovasis's Knowledge of Patent Infringement

33. On July 5, 2018, RSB sent a notice letter to Innovasis including examples of Innovasis's patent infringement with respect to the '537 Patent. RSB further indicated its willingness to engage in meaningful licensing discussions. RSB identified the Ax® Stand-Alone ALIF System as infringing at least claims 1 and 21 of the '537 Patent, providing a copy of the '537 Patent and a preliminary infringement chart mapping features of the Ax® Stand-Alone ALIF System to limitations of certain claims in the '537 Patent.

34. Innovasis responded to RSB on August 2, 2018, indicating, among other things, its unwillingness to engage in meaningful licensing discussions with RSB.

35. On May 3, 2021, RSB sent a second notice letter to Innovasis, notifying Innovasis that the U.S. Patent Trial and Appeal Board affirmed the patentability of all challenged claims of the '537 Patent in IPR2020-00264.

36. In its May 3, 2021, letter, RSB reiterated that the Ax® Stand-Alone ALIF System had infringed and continues to infringe at least claims 1 and 21 of the '537 Patent. RSB once again invited Innovasis to engage in meaningful licensing discussions regarding the Asserted Patent.

37. Innovasis responded to RSB on June 1, 2021, once again indicating its unwillingness to engage in meaningful licensing discussions with RSB.

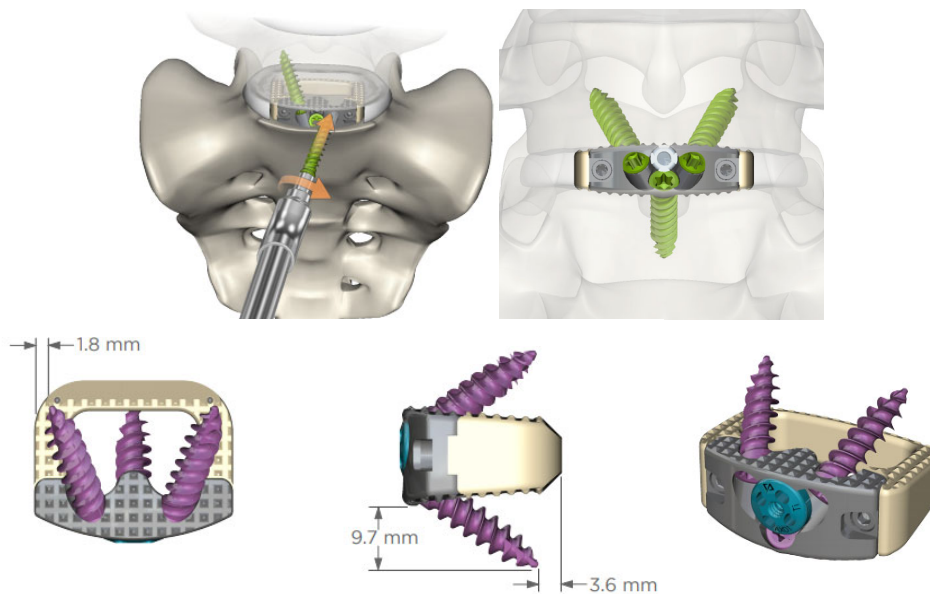
38. On November 9, 2023, RSB sent a third notice letter to Innovasis, notifying Innovasis that Innovasis' arguments regarding invalidity and non-infringement were substantially similar to those unsuccessfully made by DePuy in front of a jury. RSB also notified Innovasis that

it had recently filed a complaint against Orthofix/SeaSpine in the Eastern District of Texas after similar licensing negotiation efforts were unsuccessful.

39. Innovasis responded to RSB on December 12, 2023, further indicating its unwillingness to engage in meaningful licensing discussions with RSB.

The Accused Product

40. Innovasis's Ax® Stand-Alone ALIF System is illustrated below.



41. The Ax® Stand-Alone ALIF System is an intervertebral body fusion device intended to stabilize a spinal segment to promote fusion using bone graft to restrict motion and decrease pain. The device consists of a titanium faceplate with an Invibio PEEK-OPTIMA HA Enhanced body. HA enhanced PEEK is integrated with osteoconductive hydroxyapatite (HA). The implants have a tapered leading edge which aids in implant insertion due to limited anatomical space, and they feature a bi-convex profile to match the anatomy and anti-migration features to ensure implant stability during the fusion process. The large graft cavity provides increased volume for autograft loading.

42. The Ax® Stand-Alone ALIF System is referred to herein as the “Accused Product.”

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

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

44. Upon information and belief, Innovasis has infringed directly and indirectly, literally and under the doctrine of equivalents, at least claims 1, 14, and 21 of the ’537 Patent by making, using, selling, and/or offering for sale the Accused Product.

45. 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.

46. The Accused Product contains each of the above limitations. *See, e.g., Exhibit E.*

47. The Accused Product is a bone stabilization system with base plates having a top surface, a bottom surface and more than one bone screw hole.

48. The Accused Product further includes a base plate 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.

49. The Accused Product has 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.

50. The Accused Product has 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.

51. The Accused Product also has 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.

52. The Accused Product has 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.

53. Claim 14 of the '537 Patent claims the system as set forth in claim 1, wherein:

each of the plurality of bone screw holes extends at least partially through the first or second end;

the first end comprising a first bone engaging region fully extending uninterrupted between lateral extents of the first end; and

the second end comprising a second bone engaging region fully extending uninterrupted between lateral extents of the second end.

54. The Accused Product contains each of the above limitations. *See, e.g.*, **Exhibit E**.

55. The Accused Product is the stabilization system as set forth in claim 1, wherein each of the plurality of bone screw holes extends at least partially through the first or second end.

56. The Accused Product contains a first end comprising a first bone engaging region fully extending uninterrupted between lateral extents of the first end.

57. The Accused Product also includes a second end comprising a second bone engaging region fully extending uninterrupted between lateral extents of the second end.

58. 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.

59. The Accused Product contains each of the above limitations. *See, e.g.*, **Exhibit E**.

60. The Accused Product is a bone stabilization plate system that anchors between side surfaces of a first and second adjacent vertebral bone.

61. The Accused Product is 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 there through, and a bottom surface.

62. The base plate of the Accused Product 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.

63. 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.

64. 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.

65. Upon information and belief, Innovasis markets and sells the Accused Product in the United States to its partners, clients, customers, and end users who use the Accused Product across the country and in this District.

66. Upon information and belief, since at least the date of RSB's notice of infringement regarding the '537 Patent on July 5, 2018, Innovasis has induced 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, Innovasis's partners, clients, customers, and end users, whose use of the Accused Product constitutes direct infringement of at least one claim of the '537 Patent.

67. In particular, Innovasis's actions that aided and abetted others such as its partners, clients, customers and end users to infringe include advertising and distributing the Accused Product and providing instruction materials, training, and services regarding the Accused Product.

68. Upon information and belief, Innovasis has engaged in such actions with specific intent to cause infringement or with willful blindness to the resulting infringement, because Innovasis 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.

69. Upon information and belief, Innovasis 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 the Accused Product to be especially made or adapted for use to infringe the '537 Patent. The Accused Product is a material component for use in practicing the '537 Patent, is specifically made, and is not a staple article of commerce suitable for substantial non-infringing use.

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

71. Upon information and belief, Innovasis's infringement of the '537 Patent has been willful. Innovasis 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 Innovasis that RSB was willing to engage in

meaningful licensing discussions, Innovasis instead continued 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 issues triable to a jury.

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 Innovasis as follows:

- A. An adjudication that Innovasis has infringed the Asserted Patent;
- B. An award of damages to be paid by Innovasis adequate to compensate RSB for Innovasis's past infringement of the Asserted Patent, 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;
- C. An adjudication that Innovasis's infringement has been willful and an award of treble damages;
- D. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of RSB's reasonable attorneys' fees; and
- E. An award to RSB of such further relief at law or in equity as the Court deems just and proper.

April 10, 2024

SNELL & WILMER L.L.P.

/s/ Mark O. Morris

Mark O. Morris

Attorneys for Plaintiff

Erik B. Milch
Elizabeth Shrieves
Sarah W. Ghivizzani
PROSKAUER ROSE LLP
1001 Pennsylvania Ave., NW
Suite 600 South
Washington, DC 20004-2533
(202) 416-6899

Baldassare Vinti
Joseph M. Drayton
Connor J. Villar
PROSKAUER ROSE LLP
Eleven Times Square
New York, NY 10036-8299
(212) 969-2900

Plaintiff's Address:

1877 Eagle Pass
Wooster, OH 44691