IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff RSB Spine, LLC ("RSB" or "Plaintiff") hereby asserts claims against Defendant Medacta USA, Inc. ("Medacta" or "Defendant") for infringement of U.S. Patent Nos. 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, Medacta is a corporation organized and existing under the laws of Delaware with its place of business at 1556 West Carroll Avenue, Chicago, IL 60607-1030.

4. Upon information and belief, Medacta manufactures and distributes spinal therapy products, including anterior lumbar interbody fusion devices.

5. Upon information and belief, Medacta 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 that incorporate infringing technology, knowing that they will 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. Medacta 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, Medacta has sufficient minimum contacts within the State of Delaware because Medacta purposefully availed itself of the privileges of conducting business in the State of Delaware, Medacta regularly conducts and solicits business within the State of Delaware, and RSB's causes of action arise directly from Medacta'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 both 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 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 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 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. Patents 6,984,234 and 9,713,537 (the "Asserted Patents"). The product packaging, product inserts, and RBS'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 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 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 of the device to properly bear the weight of adjacent vertebral bodies.

The '234 Patent

25. 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.

26. 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 A**.

27. 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.

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

The ’537 Patent

29. 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.

30. 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 on United States Patent Application No. 15/413,945, filed on January 24, 2017. A copy of the ’537 Patent is attached as **Exhibit B**.

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

The Accused Product

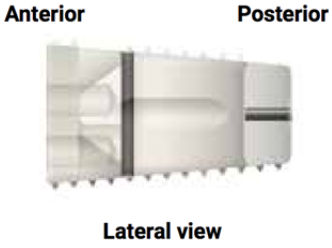
32. Medacta’s MectaLIF Anterior Stand Alone – Flush is illustrated below.

MECTALIF ANTERIOR STAND-ALONE SCREWS PRIMARY

ENHANCED SCREW	SIZE	BLUNT TIP SCREW
03.30.111	Screw Ø5 x 25mm (1x)	03.30.101
03.30.112	Screw Ø5 x 30mm (1x)	03.30.102
03.30.113	Screw Ø5 x 35mm (1x)	03.30.103
03.30.114	Screw Ø5 x 40mm (1x)	03.30.107
03.30.131	Screw Ø5 x 25mm (2x)	03.30.121
03.30.132	Screw Ø5 x 30mm (2x)	03.30.122
03.30.133	Screw Ø5 x 35mm (2x)	03.30.123
03.30.134	Screw Ø5 x 40mm (2x)	03.30.127

MECTALIF ANTERIOR STAND-ALONE SCREWS REVISION

ENHANCED SCREW	SIZE	BLUNT TIP SCREW
03.30.115	Screw Ø5,5 x 25mm (1x)	03.30.104
03.30.116	Screw Ø5,5 x 30mm (1x)	03.30.105
03.30.117	Screw Ø5,5 x 35mm (1x)	03.30.106
03.30.118	Screw Ø5,5 x 40mm (1x)	03.30.108
03.30.135	Screw Ø5,5 x 25mm (2x)	03.30.124
03.30.136	Screw Ø5,5 x 30mm (2x)	03.30.125
03.30.137	Screw Ø5,5 x 35mm (2x)	03.30.126
03.30.138	Screw Ø5,5 x 40mm (2x)	03.30.128



Lateral view

33. The MectaLIF Stand Alone – Flush is a modular anterior interbody fusion device designed for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. The MectaLIF Stand Alone – Flush design creates a zero-profile construct with minimum geometrical impact. It features exclusive divergent and convergent screws and a horizontal screw angle that reduces screw back outs.

34. The MectaLIF Stand Alone – Flush is referred to herein as "the Accused Product".

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

35. RSB realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 34 of the Complaint as though fully set forth herein.

36. Upon information and belief, Medacta has infringed and continues to infringe directly and indirectly, literally and under the doctrine of equivalents, at least claim 35 of the '234 Patent by making, using, selling, and/or offering for sale the Accused Product.

37. 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.

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

39. The Accused Product includes 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.

40. 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.

41. The Accused Product has first and second bone screws for extending into the first and second bone bodies.

42. 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.

43. Upon information and belief, Medacta 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.

44. Upon information and belief, Medacta 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, Medacta’s partners, clients, customers, and end users, whose use of the Accused Product constitutes direct infringement of at least one claim of the ’234 Patent.

45. In particular, Medacta’s actions that aid and abet 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.

46. Upon information and belief, Medacta 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 the Accused Product to be especially made or adapted for use to infringe the ’234 Patent. The Accused Product is a material component for use in practicing the ’234 Patent, is specifically made, and is not a staple article of commerce suitable for substantial non-infringing use.

47. As a consequence of each of Medacta’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.

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

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

49. RSB realleges and incorporates 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, Medacta has and continues to directly and indirectly infringe, 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 Product.

51. 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.

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

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

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

61. The Accused Product includes 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.

62. 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.

63. The Accused Product includes 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.

64. 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.

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

66. The Accused Product anchors between side surfaces of a first and second adjacent vertebral bone.

67. 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 therethrough, and a bottom surface.

68. 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.

69. 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.

70. 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.

71. Upon information and belief, Medacta 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.

72. Upon information and belief, Medacta 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, Medacta’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.

73. In particular, Medacta’s actions that aid and abet 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.

74. Upon information and belief, Medacta is liable for contributory infringement of the ’537 Patent under 35 U.S.C. § 271(c) for 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.

75. As a consequence of each of Medacta’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.

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

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 Medacta as follows:

A. An adjudication that Medacta has infringed the Asserted Patents;

B. A permanent injunction against Medacta, 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 Asserted Patents;

C. An award of damages to be paid by Medacta adequate to compensate RSB for Medacta's past infringement of the Asserted Patents, and any continuing or future infringement through the date such judgment is entered, including 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. 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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