IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GLOBUS MEDICAL, INC.	
Plaintiff, v.	Civil Action No JURY TRIAL DEMANDED
LIFE SPINE, INC.	JOKI IKIAL DEMANDED
Defendant.	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Globus Medical, Inc. ("Globus") respectfully brings this Complaint for Patent Infringement against Defendant Life Spine, Inc. ("Life Spine") and alleges as follows:

NATURE OF THE CASE

1. Globus brings this action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271 et seq.

PARTIES

- 2. Globus is a corporation organized under the laws of the State of Delaware with its principal place of business located at 2560 General Armistead Avenue, Audubon, Pennsylvania 19403.
- 3. Life Spine is a corporation organized under the laws of the State of Delaware with its principal place of business located at 13951 S Quality Drive, Huntley, Illinois 60142.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

- 5. This Court has personal jurisdiction over Life Spine because it is a Delaware corporation and maintains a registered agent in this judicial district.
- 6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)(2) and 1400(b) because Life Spine is subject to this Court's personal jurisdiction and therefore resides in this judicial district pursuant to 28 U.S.C. § 1391(c).

FACTUAL ALLEGATIONS

A. <u>Technology Background</u>

- 7. Globus is one of the world's leading musculoskeletal implant manufacturers, developing and selling a wide array of spinal products and prostheses. Founded in 2003, Globus's focus on advancing spinal surgery has made it one of the fastest growing companies in the history of orthopedics. Globus uses superior engineering and technology to achieve pain free, active lives for all patients with spinal disorders. Since its inception, Globus has been a leading innovator and received more than 150 patents in the expandable space.
- 8. Globus manufactures and sells expandable spinal implants used in fusion procedures. A spinal fusion procedure is a type of surgery used to treat painful spine conditions, such as degenerative disc disease, arising from weakening of the intervertebral discs that cushion the vertebrae. The goal of a fusion procedure is to restore the distance between the adjacent vertebrae in the spine segment using an interbody spacer. Once the spacer is in place between the adjacent vertebrae, bone will grow into and through the area between the adjacent vertebrae causing a "fusion" of the two adjacent bones into a single bone. The spacer remains in the body to maintain the distance between the adjacent vertebrae as bone grows and fusion occurs. With fusion of the adjacent vertebrae into a single bone, the spine segment is immobilized, eliminating the cause of the patient's pain.

- 9. Spacers have been around for decades. Initially, physicians harvested bone from a patient's hip to use as a spacer. Later, synthetic spacers and "intervertebral cages" became more commonplace.
- 10. In January 2011, Globus launched CALIBER®, its first expandable intervertebral implant. Unlike "static" spacers, which are pre-sized at a fixed height and "hammered" into the intervertebral space, the CALIBER® implant enters the intervertebral space in a contracted configuration and is expanded only after placement. This approach is less traumatic for the adjacent vertebrae.
- 11. Globus subsequently released the CALIBER®-L product. Unlike the CALIBER® implant, which is designed for a transforaminal approach (*i.e.*, from the back of the spine), the CALIBER®-L expandable implant is designed for a lateral approach (*i.e.*, from the side of the spine).
- 12. Globus continued to innovate and released a number of expandable implant products including the RISE® and ELSA® families of expandable implant products. The RISE® IntraLIF® products, for instance, were designed to be delivered laparoscopically via minimally invasive surgical techniques yet still have a sufficiently wide range of expansion. The ELSA® products include integrated fixation that allow the implant to be attached to the vertebrae with screws.



Figure 1: RISE® implant



Figure 2: ELSA® implant

B. The Patents-in-Suit

- 13. The technology claimed in this case relates to intervertebral expandable implants, and surgical systems and methods utilizing such implants.
- 14. Globus is the assignee of U.S. Patent No. 8,845,731 (the "'731 Patent"), U.S. Patent No. 8,845,732 (the "'732 Patent"), U.S. Patent No. 9,402,739 (the "'739 Patent"), U.S. Patent No. 9,956,087 (the "'087 Patent"), U.S. Patent No. 10,137,001 (the "'001 Patent"), U.S. Patent No. 10,925,752 (the "'752 Patent"), and U.S. Patent No. 10,973,649 (the "'649 Patent") (together, the "Patents-in-Suit"). Globus owns all right, title, and interest in and to the Patents-in-Suit and possesses all rights of recovery.
 - 15. All of the Patents-in-Suit relate to technology developed in-house by Globus.
- 16. The '731 Patent was issued by the U.S. Patent and Trademark Office ("PTO") on September 30, 2014, from application no. 12/875,637 filed on September 3, 2010. Under 35 U.S.C. § 154(b), the term of this patent was extended by 118 days. A true and correct copy of the '731 Patent is attached hereto as Exhibit A.
- 17. The '732 Patent was issued by the PTO on September 30, 2014, from an application filed on June 25, 2012, which was a continuation-in-part of application no. 12/875,637 filed on September 30, 2010 (which issued as the '731 Patent). Under 35 U.S.C. § 154(b), the term of this patent was extended by 53 days. The patent is also subject to a terminal disclaimer. A true and correct copy of the '732 Patent is attached hereto as Exhibit B.

- 18. The '739 Patent was issued by the PTO on August 2, 2016, from an application filed on February 7, 2014. Under 35 U.S.C. § 154(b), the term of this patent was extended by 51 days. A true and correct copy of the '739 Patent is attached hereto as Exhibit C.
- 19. The '087 Patent was issued by the PTO on May 1, 2018, from an application filed on May 2, 2016, which was a continuation-in-part of application no. 15/097,466 filed on April 13, 2016, which was a continuation-in-part of application no. 14/802,229 filed on July 17, 2015. Under 35 U.S.C. § 154(b), the term of this patent was extended by 19 days. A true and correct copy of the '087 Patent is attached hereto as Exhibit D.
- 20. The '001 Patent was issued by the PTO on November 27, 2018, from an application filed on August 22, 2014, which was a continuation of application no. 13/531,943 filed on June 25, 2012 (which issued as the '732 Patent), which was a continuation-in-part of application no. 12/875,637 filed on September 3, 2010 (which issued as the '731 Patent). Under 35 U.S.C. § 154(b), the term of this patent was extended by 61 days. A true and correct copy of the '001 Patent is attached hereto as Exhibit E.
- 21. The '752 Patent was issued by the PTO on February 23, 2021, from an application filed on September 11, 2018, which was a continuation of application no. 15/158,829 filed on May 19, 2016, which was a continuation of application no. 14/109,429 filed on December 17, 2013, which was a division of application no. 12/875,818 filed on September 3, 2010. Under 35 U.S.C. § 154(b), the term of this patent was extended by 14 days. A true and correct copy of the '752 Patent is attached hereto as Exhibit F.
- 22. The '649 Patent was issued by the PTO on April 13, 2021, from an application filed on December 21, 2016, which was a continuation of application no. 13/961,603 filed on May 19, 2016, which was a continuation-in-part of application no. 13/531,844 filed on June 25,

2012, which was a continuation-in-part of application no. 12/875,637 filed on September 3, 2010 (which issued as the '731 Patent). Under 35 U.S.C. § 154(b), the term of this patent was extended by 17 days. A true and correct copy of the '649 Patent is attached hereto as Exhibit G.

23. Globus currently sells products, such as those described herein, marked with all Patents-in-Suit.

C. The Accused Products

- 24. Life Spine manufactures and sells expandable implants for spinal fusion surgeries under at least the PROLIFT product line.
- 25. Life Spine launched the initial PROLIFT implant in 2016. The PROLIFT implant is available in at least three different sizes: 8 millimeters, 10 millimeters, and 12 millimeters. The initial PROFLIT is sometimes called the ProLift Expandable Spacer System.
- 26. Life Spine studied existing patents in the spinal fusion space when developing PROLIFT, which "show[ed] devices that feature an upper endplate, lower endplate, base ramp, nose ramp, and a screw that is used to expand" the implant. Life Spine then "included these same features in its design of the ProLift."
- 27. Life Spine subsequently launched the PROLIFT Lateral and PROLIFT Lateral Fixated implants. The PROLIFT Lateral and PROLIFT Lateral Fixated implants are also sold in various sizes. PROLIFT Lateral is sometimes called the ProLift Lateral Expandable Spacer System, and PROLIFT Lateral Fixed is sometimes called the ProLift Lateral Fixated Expandable Spacer System.
- 28. Life Spine recently launched the PROLIFT Lateral Helo, sometimes called the ProLift Lateral Helo Expandable Spacer System.

- 29. The PROLIFT, PROLIFT Lateral, PROLIFT Lateral Fixated, and PROLIFT Lateral Helo implants (together, the "Accused Products") share a few common characteristics.
- 30. First, the Accused Products comprise two endplates connected by two "wedge-shaped components," which have also been called the base ramp and nose ramp. According to Life Spine, the expansion mechanism for these products draws these wedge-shaped components "together as a means of securely pushing the implant's endplates further apart." In other words, the two ramps are closer together when the device is expanded than when it is compressed.



Figure 3: PROLIFT implant in compressed and expanded form

31. Second, the base ramp and nose ramp are connected to each other by an actuator assembly, which includes a screw. The screw fits within a threaded opening at one end of the implant and a non-threaded opening at the other end, from which it can be turned to expand or compress the implant.

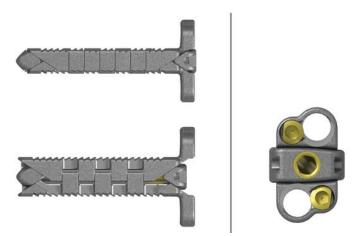


Figure 4: PROLIFT Lateral Fixated implant with non-threaded opening visible

32. Third, the outer surfaces of both endplates are textured. Texturing helps the implant grip onto the adjacent vertebral bodies. The Accused Products are also designed to allow the introduction of bone graft material *in situ* within and around the implant.



Figure 5: PROLIFT Lateral implant with textured surface and bone graft material visible

- 33. Life Spine has applied for and received Food & Drug Administration ("FDA") approval to market the Accused Products under section 510(k) of the Food, Drug, and Cosmetic Act, which provides an abbreviated process for reviewing medical devices shown to be substantially equivalent to existing devices that have already been approved. At various times, Life Spine has cited the Globus CALIBER®, RISE®, and ELSA® products as substantially equivalent predecessor devices in its 510(k) submissions to FDA.
- 34. Life Spine obtained "a patent for the original ProLift" in October 2017—U.S. Patent No. 9,801,733 (the "'733 Patent"). The '733 Patent is assigned to Life Spine; the inventors are listed as Madeline Wolters, Daniel Predick, and Michael S. Butler. Butler is Life Spine's founder and currently serves as its President and CEO.
- 35. The '733 Patent includes numerous diagrams depicting the claimed invention, including two figures providing a cross-sectional view and an exploded perspective view.

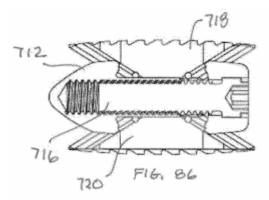


Figure 6: Cross-sectional view ('733 Patent, Fig. 86)

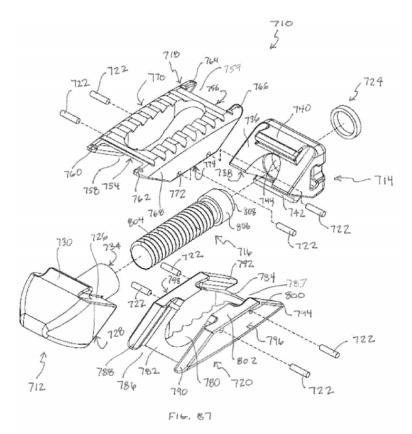


Figure 7: Exploded perspective view ('733 Patent, Fig. 87)

- 36. Substantially similar diagrams can be located in U.S. Patent No. 10,172,718 (the "'718 Patent"), a continuation of the '733 Patent and lists the same inventors, including Life Spine's President and CEO, Michael S. Butler.
- 37. Expandable implants like the Accused Products can be installed by surgical methods (the "Accused Methods") that involve the creation of an access path to the intervertebral

space, the insertion of the implant, the expansion of the implant, and the introduction of bone graft material.

- 38. Surgical instruments used for the installation of the Accused Products can include a tapered dilator for accessing the intervertebral space and a cannula for insertion of the implant.
- 39. Life Spine educates and encourages surgeons to use the Accused Products and Accused Methods. Life Spine employs sales representatives to sell PROLIFT products to medical professionals and institutions for use in spinal fusion surgeries. These sales representatives provide information to the surgeons who perform these surgeries on how to use the PROLIFT products.
- 40. Life Spine also maintains a website called XPanding Micro-Invasive Procedures at https://www.micro-invasive.com to educate surgeons on how to use its PROLIFT products with minimally invasive surgical techniques. The website includes three clinical case studies from physicians who have successfully used a PROLIFT implant.
- 41. Life Spine's XPanding Micro-Invasive Procedures website also includes a section called "MED EDU," at https://www.micro-invasive.com/med-edu, which describes the company's PULSE program, "Life Spine's premier program for physician training through personalized visits highlighted by cadaveric labs and didactic learning sessions." Through this program, Life Spine "offers a large variety of faculty led experiences" with the goal of "educat[ing] surgeons worldwide on all aspects of a surgery" using Life Spine's products. An identical description of the PULSE program appears on Life Spine's main website.
- 42. Life Spine and/or its agents, such as third-party distributors, disseminate surgical technique guides that walk surgeons through methods for installing the Accused Products.

- 43. Furthermore, Life Spine has admitted that it entered into agreements with "surgeons, and entities owned in whole or in part by the surgeons" that resulted in payment of "more than \$7 million in consulting fees, royalties, and intellectual property acquisition payments." Life Spine made this admission to settle charges by the United States, through the U.S. Attorney's Office of the Southern District of New York, that this conduct, which was allegedly done "with the knowledge, involvement, and participation" of Life Spine CEO Michael Butler and Vice President Richard Greiber, violated the False Claims Act and Anti-Kickback Statute. In connection with that settlement, Life Spine agreed to pay \$5.5 million in restitution to the United States.
- 44. Life Spine also admitted in its settlement agreement with the United States that "[m]ost of the surgeons who received these payments substantially increased their usage of Life Spine products after entering into agreements with Life Spine," and what's more, these particular surgeons "were high-volume users" that constituted "21 of the top 30 users of Life Spine products" during the 7-year period in which Life Spine made these payments. Moreover, "[w]hen surgeons' usage decreased, senior sales managers would contact the surgeons, or their distributors, to urge the surgeons to more frequently use Life Spine products." (emphases added).
- 45. In connection with his individual settlement with the United States, Life Spine CEO Michael Butler admitted that he was personally "involved in identifying and retaining some of the surgeons who served as paid consultants for Life Spine," and that he would "on occasion"

¹ The government's complaint-in-intervention was filed in July 2019 and can be found at https://www.justice.gov/usao-sdny/press-release/file/1186211/download. The quoted language in paragraphs 43-44 can be found in the settlement agreement between the United States and Life Spine, which is located at https://www.justice.gov/usao-sdny/press-release/file/1215966/download.

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contact surgeons whose usage of Line Spine products had decreased "to encourage them to increase their usage." Butler also agreed to pay \$375,000 in restitution to the United States.

- 46. All of this conduct further demonstrates Life Spine's encouragement of surgeons to use the Accused Products and Accused Methods.
- 47. The Accused Products have been extremely successful and lucrative for Life Spine. In January 2021, the company reported that it had reached sales of over 20,000 PROLIFT units. Its President and CEO, Michael Butler, described the "rapid adoption" of Life Spine's expandable technology and projected further increases in expandable technology over the next five years.
- 48. Life Spine has described PROLIFT as its "top performing line of devices" and the company's products as being used by "more than a thousand surgeons in forty-eight states."
- 49. Life Spine also announced in January 2021 that it had achieved 23% revenue growth for the first quarter of 2021 compared to the previous quarter for its lateral expandable products, the PROLIFT Lateral and PROLIFT Lateral Fixated.

COUNT I: INFRINGEMENT OF THE '731 PATENT

- 50. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 51. Life Spine has infringed at least claim 1 of the '731 Patent, pursuant to 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the Accused Products in the United States and/or by importing the Accused Products into the United States, directly and/or

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² The quoted language in paragraph 45 can be found in the settlement agreement between the United States and Butler, which is located at https://www.justice.gov/usao-sdny/press-release/file/1215981/download.

indirectly, on its own and/or through its agents. The Accused Products embody every limitation of these claims literally and/or under the doctrine of equivalents.

- 52. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '731 Patent by exemplary product PROLIFT is attached as Exhibit H. Additional infringing products and/or infringed claims of the '731 Patent will be disclosed pursuant to the Court's rules.
- 53. Life Spine has also actively induced infringement of the '731 Patent pursuant to 35 U.S.C. § 271(b) by non-party partners and distributors of the Accused Products, directly and/or indirectly, on its own and/or through its agents.
 - 54. The '731 Patent is valid and enforceable.
- 55. Life Spine has been on notice of the '731 Patent pursuant to 35 U.S.C. § 287(a) since at least November 2015, when Globus manufactured and sold the RISE® implant marked in accordance with that provision.
- 56. Life Spine also had actual knowledge of the disclosures of the '731 Patent. For example, Life Spine cited patent publication no. 2012/0330422—i.e., patent application no. 13/531,943 (which issued as the '732 Patent), which disclosed that it was a continuation-in-part of application no. 12/875,637 (which issued as the '731 Patent)—during prosecution of several of its own patents, including U.S. Patent Nos. 8,940,048, 9,034,041, 9,801,733, 10,154,911, 10,383,741, and 10,426,632, as well as the '718 Patent. These patents are assigned to Life Spine, and its President and CEO, Michael S. Butler, is named as a co-inventor. As another example, Life Spine has named RISE® as a substantially equivalent product to PROLIFT in its 510(k) submissions to FDA. As another example, Life Spine engineers studied existing patents in the spinal fusion space when developing PROLIFT.

- 57. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '731 Patent.
- 58. Life Spine's infringement of the '731 Patent has been and continues to be willful, as Life Spine had notice of the '731 Patent and deliberately continued to infringe.
- 59. As a result of Life Spine's infringement of the '731 Patent, Globus has been damaged and continues to suffer damages.
- 60. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '731 Patent and has no adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '732 PATENT

- 61. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 62. Life Spine has infringed at least claim 1 of the '732 Patent, pursuant to 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the Accused Products in the United States and/or by importing the Accused Products into the United States, directly and/or indirectly, on its own and/or through its agents. The Accused Products embody every limitation of these claims literally and/or under the doctrine of equivalents.
- 63. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '732 Patent by exemplary product PROLIFT is attached as Exhibit I.
- 64. Additional infringing products and/or infringed claims of the '732 Patent will be disclosed pursuant to the Court's rules.

- 65. Life Spine has also actively induced infringement of the '732 Patent pursuant to 35 U.S.C. § 271(b) by non-party partners and distributors of the Accused Products, directly and/or indirectly, on its own and/or through its agents.
 - 66. The '732 Patent is valid and enforceable.
- 67. Life Spine has been on notice of the '732 Patent pursuant to 35 U.S.C. § 287(a) since at least November 2015, when Globus manufactured and sold the RISE® implant marked in accordance with that provision.
- 68. Life Spine also had actual knowledge of the disclosures of the '732 Patent. For example, Life Spine cited patent publication no. 2012/0330422—*i.e.*, patent application no. 13/531,943 (which issued as the '732 Patent)—during prosecution of several of its own patents, including U.S. Patent Nos. 8,940,048, 9,034,041, 9,801,733, 10,154,911, 10,383,741, and 10,426,632, as well as the '718 Patent. These patents are assigned to Life Spine, and its President and CEO, Michael S. Butler, is named as a co-inventor. As another example, Life Spine has named RISE® as a substantially equivalent product to PROLIFT in its 510(k) submissions to FDA.
- 69. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '732 Patent.
- 70. Life Spine's infringement of the '732 Patent has been and continues to be willful, as Life Spine had notice of the '732 Patent and deliberately continued to infringe.
- 71. As a result of Life Spine's infringement of the '732 Patent, Globus has been damaged and continues to suffer damages.

72. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '732 Patent and has no adequate remedy at law.

COUNT III: INFRINGEMENT OF THE '739 PATENT

- 73. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 74. Life Spine has infringed at least claim 1 of the '739 Patent, pursuant to 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the Accused Products in the United States and/or by importing the Accused Products into the United States, directly and/or indirectly, on its own and/or through its agents. The Accused Products embody every limitation of these claims literally and/or under the doctrine of equivalents.
- 75. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '739 Patent by exemplary product PROLIFT Lateral is attached as Exhibit J.
- 76. Additional infringing products and/or infringed claims of the '739 Patent will be disclosed pursuant to the Court's rules.
- 77. Life Spine has also actively induced infringement of the '739 Patent pursuant to 35 U.S.C. § 271(b) by non-party partners and distributors of the Accused Products, directly and/or indirectly, on its own and/or through its agents.
 - 78. The '739 Patent is valid and enforceable.
- 79. Life Spine has been on notice of the '739 Patent pursuant to 35 U.S.C. § 287(a) since at least December 2018, when Globus manufactured and sold the RISE-L® implant marked in accordance with that provision.

- 80. Life Spine also had actual knowledge of the disclosures of the '739 Patent. For example, Life Spine cited patent publication no. 2015/0223946—*i.e.*, patent application no. 14/449428, which disclosed that it was a continuation-in-part of application no. 14/175,601 (which issued as the '739 Patent)—during prosecution of several of its own patents, including U.S. Patent Nos. 9,610,172 and 10,251,759. These patents are assigned to Life Spine, and its President and CEO, Michael S. Butler, is named as a co-inventor.
- 81. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '739 Patent.
- 82. Life Spine's infringement of the '739 Patent has been and continues to be willful, as Life Spine had notice of the '739 Patent and deliberately continued to infringe.
- 83. As a result of Life Spine's infringement of the '739 Patent, Globus has been damaged and continues to suffer damages.
- 84. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '739 Patent and has no adequate remedy at law.

COUNT IV: INFRINGEMENT OF THE '087 PATENT

- 85. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 86. Life Spine has infringed at least claim 1 of the '087 Patent, pursuant to 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the Accused Products in the United States and/or by importing the Accused Products into the United States, directly and/or indirectly, on its own and/or through its agents. The Accused Products embody every limitation of these claims literally and/or under the doctrine of equivalents.

- 87. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '087 Patent by exemplary product PROLIFT Lateral Fixated is attached as Exhibit K.
- 88. Additional infringing products and/or infringed claims of the '087 Patent will be disclosed pursuant to the Court's rules.
- 89. Life Spine has also actively induced infringement of the '087 Patent pursuant to 35 U.S.C. § 271(b) by non-party partners and distributors of the Accused Products, directly and/or indirectly, on its own and/or through its agents.
 - 90. The '087 Patent is valid and enforceable.
- 91. Life Spine has been on notice of the '087 Patent pursuant to 35 U.S.C. § 287(a) since at least November 2018, when Globus manufactured and sold the ELSA® implant marked in accordance with that provision.
- 92. Life Spine also had actual knowledge of the disclosures of the '087 Patent. For example, Life Spine has named ELSA® as a substantially equivalent product to PROLIFT Lateral Fixated in its 510(k) submissions to FDA.
- 93. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '087 Patent.
- 94. Life Spine's infringement of the '087 Patent has been and continues to be willful, as Life Spine had notice of the '087 Patent and deliberately continued to infringe.
- 95. As a result of Life Spine's infringement of the '087 Patent, Globus has been damaged and continues to suffer damages.

96. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '087 Patent and has no adequate remedy at law.

COUNT V: INFRINGEMENT OF THE '001 PATENT

- 97. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 98. Life Spine has actively induced infringement of at least claim 1 of the '001 Patent pursuant to 35 U.S.C. § 271(b). Life Spine actively induced surgeons to infringe the '001 Patent by using the Accused Methods to perform spinal fusion surgeries with the Accused Products.
- 99. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '001 Patent is attached as Exhibit L. Additional infringed claims of the '001 Patent will be disclosed pursuant to the Court's rules.
 - 100. The '001 Patent is valid and enforceable.
- 101. Life Spine has been on notice of the '001 Patent pursuant to 35 U.S.C. § 287(a) since at least November 2018, when Globus manufactured and sold the RISE® implant marked in accordance with that provision.
- 102. Life Spine also had actual knowledge of the disclosures of the '001 Patent. For example, Life Spine has named RISE® as a substantially equivalent product to PROLIFT in its 510(k) submissions to FDA.
- 103. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '001 Patent.
- 104. Life Spine's infringement of the '001 Patent has been and continues to be willful, as Life Spine had notice of the '001 Patent and deliberately continued to infringe.

- 105. As a result of Life Spine's infringement of the '001 Patent, Globus has been damaged and continues to suffer damages.
- 106. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '001 Patent and has no adequate remedy at law.

COUNT VI: INFRINGEMENT OF THE '752 PATENT

- 107. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 108. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 109. Life Spine has infringed at least claim 1 of the '752 Patent, pursuant to 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the Accused Products in the United States and/or by importing the Accused Products into the United States, directly and/or indirectly, on its own and/or through its agents. The Accused Products embody every limitation of these claims literally and/or under the doctrine of equivalents.
- 110. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '752 Patent by exemplary product PROLIFT is attached as Exhibit M. Additional infringing products and/or infringed claims of the '752 Patent will be disclosed pursuant to the Court's rules.
- 111. Life Spine has also actively induced infringement of the '752 Patent pursuant to 35 U.S.C. § 271(b) by non-party partners and distributors of the Accused Products, and/or indirectly, on its own and/or through its agents.
 - 112. The '752 Patent is valid and enforceable.

- 113. Life Spine has been on notice of the '752 Patent pursuant to 35 U.S.C. § 287(a) since at least July 2021, when Globus manufactured and sold the RISE® implant marked in accordance with that provision.
- 114. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '752 Patent.
- 115. Life Spine's infringement of the '752 Patent has been and continues to be willful, as Life Spine had notice of the '752 Patent and deliberately continued to infringe.
- 116. As a result of Life Spine's infringement of the '752 Patent, Globus has been damaged and continues to suffer damages.
- 117. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '752 Patent and has no adequate remedy at law.

COUNT VII: INFRINGEMENT OF THE '649 PATENT

- 118. Globus restates and incorporates by reference its allegations as set forth in the preceding paragraphs.
- 119. Life Spine has infringed at least claim 1 of the '649 Patent, pursuant to 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the Accused Products in the United States and/or by importing the Accused Products into the United States, directly and/or indirectly, on its own and/or through its agents. The Accused Products embody every limitation of these claims literally and/or under the doctrine of equivalents.
- 120. As a non-limiting example, a claim chart with a description of Life Spine's infringement of exemplary claim 1 of the '649 Patent by exemplary product PROLIFT is

attached as Exhibit N. Additional infringing products and/or infringed claims of the '649 Patent will be disclosed pursuant to the Court's rules.

- 121. Life Spine has also actively induced infringement of the '649 Patent pursuant to 35 U.S.C. § 271(b) by non-party partners and distributors of the Accused Products, and/or indirectly, on its own and/or through its agents.
 - 122. The '649 Patent is valid and enforceable.
- 123. Life Spine has been on notice of the '649 Patent pursuant to 35 U.S.C. § 287(a) since at least June 2021, when Globus manufactured and sold the RISE® implant marked in accordance with that provision.
- 124. Life Spine committed the foregoing infringing activities without license from Globus and with notice of the '649 Patent.
- 125. Life Spine's infringement of the '649 Patent has been and continues to be willful, as Life Spine had notice of the '649 Patent and deliberately continued to infringe.
- 126. As a result of Life Spine's infringement of the '649 Patent, Globus has been damaged and continues to suffer damages.
- 127. The acts of infringement by Life Spine will continue unless enjoined by the Court. Globus has been and will continue to be irreparably harmed and damaged by Life Spine's infringement of the '649 Patent and has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Globus respectfully requests entry of judgment in its favor and against Life Spine as follows:

- a. Entry of judgment in favor of Globus and against Life Spine on all counts;
- b. Entry of judgment that Life Spine has infringed the Patents-in-Suit;

- c. An order permanently enjoining Life Spine, together with its officers, directors, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them, from infringing the Patents-in-Suit;
- d. An award of compensatory damages adequate to compensate Globus for Life Spine's infringement of the Patents-in-Suit, in no event less than a reasonable royalty;
- e. An award of treble damages for willful infringement pursuant to 35 U.S.C. § 284;
- f. An award to Globus of its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, based on this being an exceptional case;
- g. An award of expenses and costs incurred by Globus in connection with this action;
- h. An award of pre-judgment and post-judgment interest;
- i. An award of any other relief to which Globus is entitled.

JURY DEMAND

Globus demands a jury trial on all issues so triable in this Complaint.

Dated: October 13, 2021

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