

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

MIMEDX GROUP, INC.

Plaintiff

-vs.-

TISSUE TRANSPLANT TECHNOLOGY, LTD.
d/b/a BONE BANK ALLOGRAFTS, and TEXAS
HUMAN BIOLOGICS, LTD.

Defendants.

Civil Action No. 1:14cv00464

FIRST AMENDED COMPLAINT

(JURY TRIAL DEMANDED)

Plaintiff MiMedx Group, Inc. (“MiMedx” or “Plaintiff”) files this Complaint against Defendants Tissue Transplant Technology, Ltd. (“Tissue Transplant”) d/b/a Bone Bank Allografts (collectively, “Bone Bank”) and Texas Human Biologics, Ltd. (“THB”), (collectively, “Defendants”) and, in support thereof, alleges as follows:

NATURE AND BASIS OF ACTION

1. This is a civil action for Defendants’ infringement of United States Patent Nos. 8,597,687 and 8,709,494 (collectively, the “Patents-in-Suit”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*

2. MiMedx seeks, among other things, temporary, preliminary and permanent injunctive relief, monetary damages, punitive damages, and recovery of MiMedx’s costs and reasonable attorneys’ fees incurred in connection with this action.

PARTIES

3. Plaintiff MiMedx is a corporation organized and existing under the laws of the State of Florida and maintains its headquarters and principal place of business at 1775 West Oak Commons Ct., Marietta, Georgia 30062.

4. Upon information and belief, Tissue Transplant is organized and existing under the laws of the State of Texas and maintains its headquarters and principal place of business at 4808 Research Drive, San Antonio, Texas 78240.

5. Tissue Transplant does business as Bone Bank Allografts within this judicial district and elsewhere.

6. Upon information and belief, Bone Bank is a manufacturer and distributor of amnion-based allografts and is in the business of, among other things, marketing, distributing, offering to sell, and selling its tissue graft products including SteriShield I[™] Single Layer Protective Amnion Patch (“SteriShield I[™]”) and SteriShield II[™] Dual Layer Protective Amnion Patch (“SteriShield II[™]”) in the United States.

7. Upon information and belief, THB is organized and existing under the laws of the State of Texas and maintains its headquarters and principal place of business at 14805 Omicron Drive, Suite 102, San Antonio, Texas.

8. Upon information and belief, THB is a subsidiary of Tissue Transplant.

9. Upon information and belief, THB operates as a human tissue sterilizing and processing facility.

10. Upon information and belief, Vivex Biomedical, Inc. (“Vivex”) is a corporation organized and existing under the laws of the State of Georgia and maintains its headquarters and principal place of business at 1755 West Oak Parkway, Marietta, GA 30062.

11. Upon information and belief, Vivex is a biomaterials manufacturer and developer that is in the business of developing, marketing, distributing, offering to sell, and selling its tissue graft products including Cygnus Solo™ and Cygnus™ in the United States.

12. Upon information and belief, the SteriShield I™ and SteriShield II™ tissue graft products are made by THB, and, in turn, distributed by Bone Bank.

13. Upon information and belief, the Cygnus Solo™ and Cygnus™ tissue graft products are made by THB and/or Bone Bank, and, in turn, distributed by Vivex.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 because this case arises under the United States Patent Act, 35 U.S.C. §§ 100, *et seq.*

15. This Court has personal jurisdiction over the Defendants because Defendants transact business within the State of Texas including, but not limited to, contracting to supply goods or services in the State of Texas, engaging in acts of patent infringement within the State of Texas, engaging in acts outside the State of Texas causing injury within the State, and engaging in tortious acts within the State of Texas. Defendants have purposefully and voluntarily placed their products, and/or caused their products to be placed, into the stream of commerce with the expectation that they will be purchased by consumers in this District. As such, Defendants have established minimum contacts with the forum such that the exercise of jurisdiction over them would not offend traditional notions of fair play and substantial justice.

16. This Court has personal jurisdiction over Defendant Bone Bank because Bone Bank has continuous and systematic contacts within this State. Bone Bank: (1) has a corporate presence in this State, including offices, real property, personal property, and employees;

(2) intentionally and actively markets and provides its tissue-based products including SteriShield I™ and SteriShield II™ to residents of this State; (3) maintains an active sales force in this State; and (4) enjoys substantial revenues from sales of its products and services in this State.

17. This Court has personal jurisdiction over Defendant THB because THB has continuous and systematic contacts within this State. THB: (1) has a corporate presence in this State, including offices, real property, personal property, and employees; (2) intentionally and actively markets and provides its services and processed tissue to residents of this State; and (3) enjoys substantial revenues from sales of its products and services in this State.

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400.

BACKGROUND

I. MiMEDX AND ITS PRODUCTS

19. MiMedx develops, manufactures and markets innovative and unique regenerative bioactive products and bioimplants processed from placental human amniotic membrane.

20. MiMedx's product lines include EpiFix® and AmnioFix®, which are tissue grafts processed from human amniotic membrane that is derived from donated placentas using MiMedx's proprietary technology.

21. MiMedx processes the human amniotic membrane through a proprietary system to produce a safe and effective tissue product, which is commonly referred to as an "allograft."

22. MiMedx's products are utilized in a vast number of clinical treatments including, but not limited to, advanced wound care, orthopedic/spine surgery, and sports medicine applications. In each of these areas, and many more, MiMedx's products help to reduce inflammation, enhance healing, and reduce scar tissue formation, among other benefits.

II. THE PATENTS-IN-SUIT

23. MiMedx has an extensive patent portfolio, including the Patents-in-Suit, covering placental tissue-based products.

24. On December 3, 2013, the United States Patent and Trademark Office (“USPTO”) duly and legally issued United States Patent No. 8,597,687 (the “’687 patent”), entitled “Methods for Determining the Orientation of a Tissue Graft.” The ’687 patent names John Daniel as an inventor.

25. The ’687 patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the ’687 patent and pursue any and all causes of actions and remedies, either legal and/or equitable, related thereto. A true and correct copy of the ’687 patent is attached herein as Exhibit A.

26. On April 29, 2014, the USPTO duly and legally issued United States Patent No. 8,709,494 (the “’494 patent”), entitled “Placental Tissue Grafts.” The ’494 patent names John Daniel as an inventor.

27. The ’494 patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the ’494 patent and pursue any and all causes of actions and remedies, either legal and/or equitable, related thereto. A true and correct copy of the ’494 patent is attached herein as Exhibit B.

III. INFRINGEMENT OF THE PATENTS-IN-SUIT BY DEFENDANTS

28. Upon information and belief, THB locates and screens tissue donors and processes and makes tissues for allografts.

29. Upon information and belief, THB and Bone Bank are engaged in a partnership through which THB processes and prepares Bone Bank's SteriShield ITM and SteriShield IITM tissue graft products to be sold and used in the United States and in this judicial district.

30. Upon information and belief, Bone Bank markets, sells, and/or offers to sell the SteriShield ITM and SteriShield IITM products in the United States and in this judicial district.

31. Upon information and belief, the SteriShield ITM product is a tissue graft product which includes a single layer of amnion.

32. Upon information and belief, the SteriShield ITM product had and/or continues to have an asymmetric label on a portion of at least one side of the tissue graft to allow direct visual determination of the orientation of the tissue graft.

33. Upon information and belief, the SteriShield IITM product is a tissue graft product which includes at least two layers of amnion.

34. Upon information and belief, Bone Bank and THB each has infringed and/or continues to infringe one or more claims of the '687 patent by manufacturing, using, selling, and/or offering for sale in the United States and in this judicial district the SteriShield ITM product.

35. Upon information and belief, Bone Bank and THB each has infringed and/or continues to infringe one or more claims of the '494 patent by manufacturing, using, selling, and/or offering for sale in the United States and in this judicial district the SteriShield IITM product.

36. Upon information and belief, THB and/or Bone Bank provide processed tissue graft products to Vivex. Vivex markets, sells, and/or offers for sale these tissue graft products as Cygnus Solo[™] and Cygnus[™] in the United States and in this judicial district.

37. Upon information and belief, the Cygnus Solo[™] product includes a single layer of amnion.

38. Upon information and belief, the Cygnus Solo[™] product has been and/or continues to have an asymmetric label on a portion of at least one side of the tissue graft to allow direct visual determination of the orientation of the tissue graft.

39. Upon information and belief, the Cygnus[™] tissue graft product includes at least two layers of amnion.

40. Upon information and belief, Vivex has infringed and/or continues to infringe one or more claims of the '687 patent by manufacturing, using, selling, and/or offering for sale in the United States and in this judicial district the Cygnus Solo[™] product.

41. Upon information and belief, Vivex has infringed and/or continues to infringe one or more claims of the '494 patent by manufacturing, using, selling, and/or offering for sale in the United States and in this judicial district the Cygnus[™].

42. Upon information and belief, Bone Bank has been on actual notice of the '687 patent since at least as early as January 24, 2014.

43. Additionally, upon information and belief, Defendants have had constructive knowledge of the Patents-in-Suit at least by virtue of the identification of the Patents-in-Suit on the AminoFix[®] and EpiFix[®] product labels, package information, and/or marketing materials by referencing www.mimedx.com/patents under the heading "Amniotic Membrane Allograft Product Lines."

44. Upon information and belief, Defendants have acted and continue to act without a reasonable basis for believing that they would not be liable for infringing the relevant Patents-in-Suit.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,597,687 BY THB

45. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 44 above, inclusive.

46. Upon information and belief, THB has infringed and/or continues to infringe one or more claims of the '687 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell or selling, and/or inducing same in this judicial district and/or elsewhere, the SteriShield ITM product and/or the Cygnus SoloTM product.

47. MiMedx has been damaged by THB's past and continuing infringement of the '687 patent in an amount to be determined at trial.

48. MiMedx has been and continues to be irreparably injured by THB's past and continuing infringement of the '687 patent, and THB's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

49. MiMedx is entitled to monetary damages from THB's unauthorized infringement in an amount to be determined at trial.

50. Upon information and belief, THB has had constructive knowledge of the '687 patent at least by virtue of the identification of the '687 patent on the AminoFix[®] and EpiFix[®] product labels, package information, and/or marketing materials by referencing www.mimedx.com/patents.

51. Upon information and belief, THB acted despite an objectively high likelihood that its actions constituted infringement of the '687 patent. Upon information and belief, THB's

risk of intentionally infringing the '687 patent was either known or so obvious that it should have been known to THB. Accordingly, THB's infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '687 patent, and MiMedx accordingly is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as its attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,597,687 BY BONE BANK

52. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 51 above, inclusive.

53. Upon information and belief, Bone Bank has infringed and/or continues to infringe one or more claims of the '687 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell or selling, and/or inducing same in this judicial district and/or elsewhere, the SteriShield I™ product and/or the Cygnus Solo™ product.

54. Upon information and belief, Bone Bank directly and through authorized agents, sells and offers for sale within the United States the infringing SteriShield I™ product to hospitals, physicians, clinics, and wound care centers throughout the United States.

55. MiMedx has been damaged by Bone Bank's past and continuing infringement of the '687 patent in an amount to be determined at trial.

56. MiMedx has been and continues to be irreparably injured by Bone Bank's past and continuing infringement of the '687 patent, and Bone Bank's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

57. MiMedx is entitled to monetary damages from Bone Bank's unauthorized infringement in an amount to be determined at trial.

58. Upon information and belief, Bone Bank has had constructive knowledge of the '687 patent at least by virtue of the identification of the '687 patent on the AminoFix[®] and EpiFix[®] product labels, package information and/or marketing materials by referencing www.mimedx.com/patents as well as Plaintiff providing Bone Bank actual notice of the '687 patent.

59. Upon information and belief, Bone Bank acted despite an objectively high likelihood that its actions constituted infringement of the '687 patent. Upon information and belief, Bone Bank's risk of intentionally infringing the '687 patent was either known or so obvious that it should have been known to Bone Bank. Accordingly, Bone Bank's infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '687 patent, and MiMedx accordingly is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as its attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,709,494 BY THB

60. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 59 above, inclusive.

61. Upon information and belief, THB has infringed and/or continues to infringe one or more claims of the '494 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell or selling, and/or inducing same in this judicial district and/or elsewhere, the SteriShield II[™] product and/or the Cygnus[™] product.

62. MiMedx has been damaged by THB's infringement of the '494 patent in an amount to be determined at trial.

63. MiMedx has been and continues to be irreparably injured by THB's infringement of the '494 patent, and THB's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

64. MiMedx is entitled to monetary damages from THB's unauthorized infringement in an amount to be determined at trial.

65. Upon information and belief, THB has had constructive knowledge of the '494 patent at least by virtue of the identification of the '687 patent on the AminoFix[®] and EpiFix[®] product labels, package information and/or marketing materials by referencing www.mimedx.com/patents.

66. Upon information and belief, THB acted despite an objectively high likelihood that its actions constituted infringement of the '494 patent. Upon information and belief, Bone Bank's risk of intentionally infringing the '494 patent was either known or so obvious that it should have been known to THB. Accordingly, THB's infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '494 patent, and MiMedx accordingly is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as its attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

**COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 8,709,494 BY BONE BANK**

67. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 66 above, inclusive.

68. Upon information and belief, Bone Bank has infringed and/or continues to infringe one or more claims of the '494 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell or selling, and/or inducing same in this Judicial District and/or elsewhere, the SteriShield II[™] product and/or the Cygnus[™] product.

69. Upon information and belief, Bone Bank directly and through authorized agents, sells and offers for sale within the United States the infringing SteriShield II™ product to hospitals, physicians, clinics and wound care centers throughout the United States.

70. MiMedx has been damaged by Bone Bank's infringement of the '494 patent in an amount to be determined at trial.

71. MiMedx has been and continues to be irreparably injured by Bone Bank's infringement of the '494 patent, and Bone Bank's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

72. Upon information and belief, Bone Bank has had constructive knowledge of the '494 patent at least by virtue of the identification of the '494 patent on the AminoFix® and EpiFix® product labels, package information and/or marketing materials by referencing www.mimedx.com/patents.

73. Upon information and belief, Bone Bank acted despite an objectively high likelihood that its actions constituted infringement of the '494 patent. Upon information and belief, Bone Bank's risk of intentionally infringing the '494 patent was either known or so obvious that it should have been known to Bone Bank. Accordingly, Bone Bank's infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '494 patent, and MiMedx accordingly is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as its attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

JURY DEMAND

Plaintiff demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

- A. Enter judgment that Defendants have infringed one or more of the claims of the '687 patent and that Defendants' infringement has been willful;
- B. Enter judgment that Defendants have infringed one or more of the claims of the '494 patent and that Defendants' infringement has been willful;
- C. Award Plaintiff damages in an amount to be proved at trial that will adequately compensate Plaintiff for Defendants' infringement, but under no circumstances an amount less than a reasonable royalty, as authorized by 35 U.S.C. § 284;
- D. Increase the damages sustained by Plaintiff up to three times the amount of their actual damages, as authorized by 35 U.S.C. § 284;
- E. Enjoin Defendants, and all persons acting in concert with the Defendants, from the manufacture, use, sale, offer for sale, or importation of the accused products;
- F. Award Plaintiff its attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285;
- G. Award Plaintiff prejudgment interest and costs pursuant to 35 U.S.C. § 284; and
- H. The Court grant such other, different, and additional relief as the Court deems just and proper.

Dated: June 26, 2014

Respectfully submitted,

ALSTON & BIRD LLP

/s/ Dwayne C. Norton

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 26th of June, 2014, all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document through the Court's CM/ECF system. Any other counsel of record will be served via first class mail and/or facsimile.

/s/ Dwayne C. Norton
Dwayne C. Norton