IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

GRAHAM MEDICAL TECHNOLOGIES, LLC,

Plaintiff,

Case No.

vs.

JURY TRIAL DEMANDED

VILEX IN TENNESSEE, INC. and ABRAHAM LAVI,

Defendants.
_____/

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Graham Medical Technologies, LLC ("Graham" "Patent Owner" or "Plaintiff") by its undersigned counsel, for his complaint against Defendants Vilex in Tennessee, Inc. and Abraham Lavi, alleges as follows:

NATURE OF ACTION

1. This is an action by Graham for willful infringement of United States Utility Patent No. 7,033,398, a copy of which is attached to this Complaint as **Exhibit A.** Graham seeks both an injunction and damages for violation of the United States Patent Laws, Title 35 of the United States Code.

THE PARTIES

2. Plaintiff, Graham Medical Technologies is a Michigan Domestic Limited Liability Company having a principle place of business at 16137 Leone Drive, Macomb, Michigan, 48042. Its founder, Dr. Michael E. Graham, has invented various medical devices and treatments, including a medical implant used to treat subtalar joint hyperpronation, a condition commonly known as "flat feet."

3. Defendant, Vilex in Tennessee, Inc. (a.k.a. Vilex, Inc., hereinafter "Vilex"), is a privately-owned for profit corporation incorporated in Tennessee and headquartered at 111 Moffitt Street, McMinnville, Tennessee, 37110. Vilex manufactures medical devices for upper and lower extremities.

4. Defendant Abraham "Abe" Lavi is the founder of Vilex. On information and belief, he resides at 7412 Lake Forest Glen, Lakewood Ranch, Florida 34202 and continues to work at Vilex and directs the activities of his corporation.

5. On information and belief, Dr. Lavi develops products for Vilex, trains surgeons in the use of these products and generally exerts control over Vilex, his alter ego.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to

28 U.S.C. §§ 1331 and 1338(a). This Court has ancillary jurisdiction over claims of unfair competition pursuant to 28 U.S.C. § 1338(b).

7. This court has personnel jurisdiction under Mich. Comp. Laws 600.705 and 600.715 (2015).

8. Venue is proper within this district under 28 U.S.C §§ 1391(b), 1391(c), and 1400(b).

THE TECHNOLOGY

9. The subject patent infringement litigation is directed to the subject of a procedure for the treatment and correction of subtalar joint hyperpronation commonly known as "flat feet." A sequence of views directed to and accompanying text associated with each image illustrates one preferred embodiment of the subject invention as follows:

Fig. 1

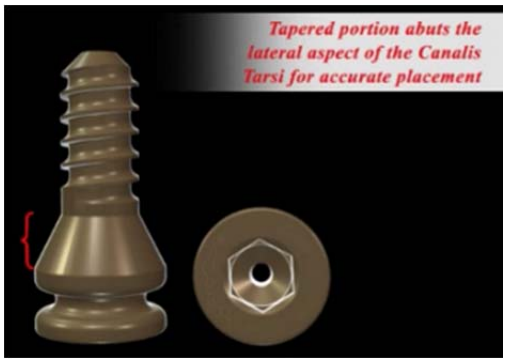


Fig. 2

Fig. 3

Fig. 4

Fig. 5

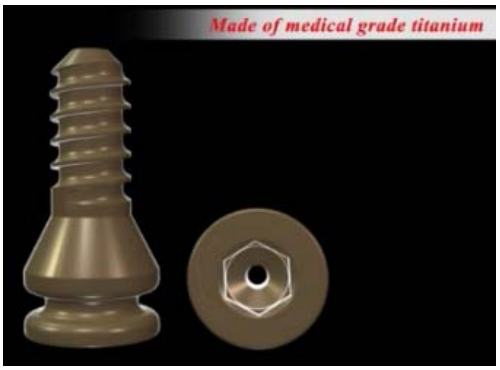


Fig. 6

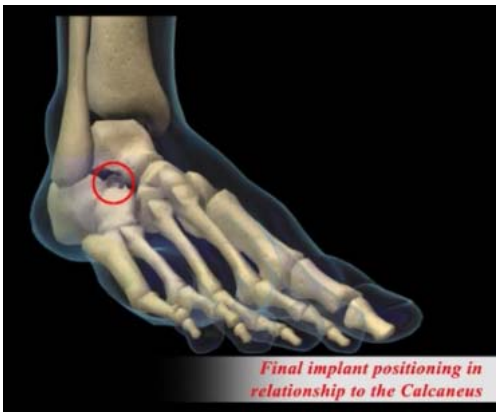


Fig. 7

Fig. 8

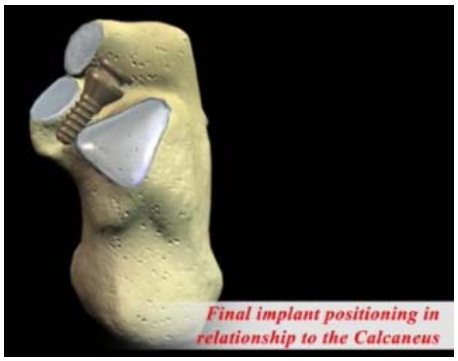


Fig. 9

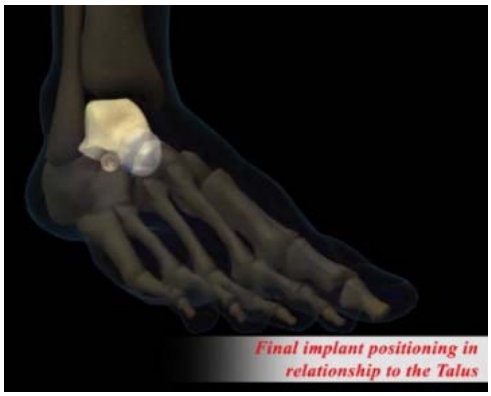


Fig. 10

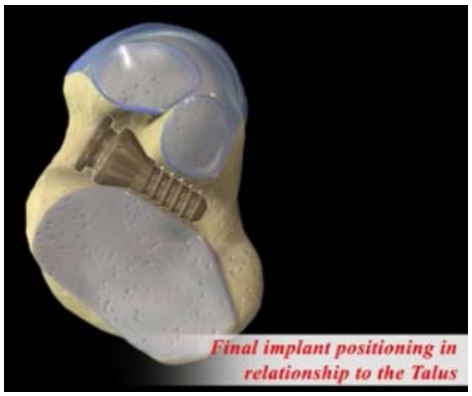


Fig. 11

THE ASSERTED PATENT

10. On February 19, 2004, Dr. Michael E. Graham filed an application for United States Letters Patent for his treatment of subtalar joint hyperpronation. This application was duly examined on the merits by the United States Patent and Trademark Office and after a period of slightly over two years U.S. Patent No. 7,033,398 ("the Patent" or the "Graham Patent") was lawfully issued to Dr. Graham on April 25, 2006, containing nineteen (19) claims. **See Exhibit A.**

11. Dr. Graham assigned his patent to Graham Medical Technologies, LLC, the plaintiff in this lawsuit, who is currently the owner of the entire right, title and interest to and in United States Patent No. 7,033,398; which patent is valid and subsisting.

12. The Graham patented method has achieved wide acclaim in the United States, and around the world, as a leading treatment for subtalar joint hyperpronation.

13. Graham does not license its patented method but directs the manufacture of surgical implants used in its method, offers seminars to train surgeons in the proper surgical application of the patented method and maintains a network by which the implants are distributed throughout the United States and around the world.

THE ACCUSED METHOD

14. Defendant, Vilex, manufactures, or has manufactured, a subtalar joint hyperpronation kit of insertion devices, as shown in **Exhibit B,** and promotes and trains surgeons with respect to a proper surgical use of the devices in an operative procedure.

15. The Vilex treatment method employs an implant for anatomical alignment of a patient's ankle bone and on November 5, 2014, Vilex filed a U.S. Trademark Application No. 86445580 for the mark "TALEX" to be used in

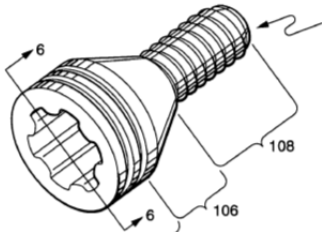
association with marketing the Vilex implant and procedure of surgical use. This Vilex application for Federal registration claims an intent to use the TALEX name in association with the Vilex surgical implant device and method in the United States and upon information and belief such use as now taken place in the United States.

16. The Vilex TALEX subtalar ankle joint hyperpronation devices, with surgical instructions for proper implanting into a human's ankle bone, are marketed and distributed throughout the United States, primarily through sales representatives.

17. Vilex sales representatives, located within this jurisdiction, distribute the Vilex treatment in Michigan.

18. Defendants offer training and support services to surgeons in Michigan who wish to use the Vilex treatment.

19. While the claims define the patented invention, a comparison of a figure from Graham's '398 patent with the Vilex infringing implant, show below, is informative:



U.S. Pat. 7,033,398, Fig. 3

Vilex infringing implant. Ex. B.

COUNT I: INFRINGEMENT OF CLAIM 1 OF U.S. PATENT NO. 7,033,398

20. Graham restates the allegations set forth in the paragraphs 1 through 19 above as if fully set forth herein.

21. Claim 1 of U.S. Patent No. 7,033,398 ("Claim 1"), begins as follows::

> A method of correcting anatomical alignment of a patient's ankle bone structure comprising: inserting an implant into a sinus tarsi of a

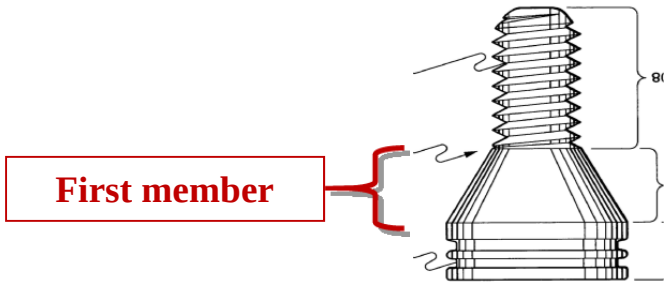
22. This first portion of Claim 1 corresponds to the Vilex instructed procedure. See, for example, "A New Choice for Talotarsal Stabilization and Flatfoot Correction" which includes "penetration into the sinus tarsi," Exhibit B, panel 3.

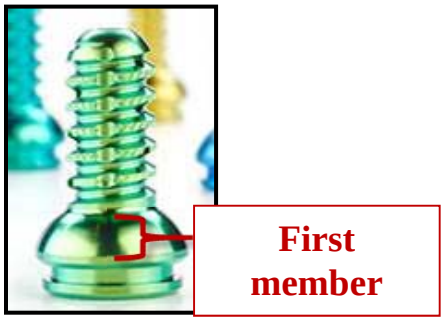
23. The next element of Claim 1 is an implant with a "first member:"

> . . . said implant comprising, a first member having an outer surface generally configured in the shape of a right conical frustum having a base portion and a top portion, and being inserted into a sinus region of the patient's sinus tarsi; . . .

24. The first member is "generally configured" in the shape of right conical frustum and "generally configured" is defined, in part, in U.S. Pat. 7,033,398, col. 8, lines 3-6: "[T]he first member, or generally frustum shaped portion, may be concave or <u>convex</u> as appropriate, however, the general funnel configuration will remain (emphasis added)."

25. The "first member" element of Claim 1 corresponds to the convex frustum shaped portion of the Vilex implant as shown in Exhibit B, panel 2, reproduced below:



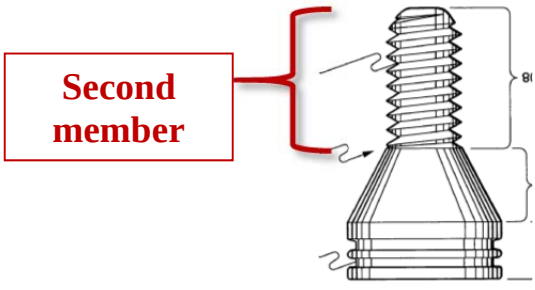


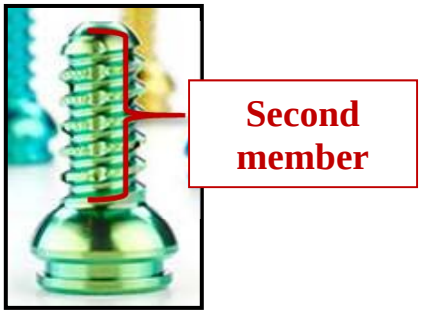
U.S. Pat. 7,033,398, Fig. 4 Vilex infringing implant. Ex. B

26. The next element of Claim 1 is the implant's "second member:"

> . . . a second member, axially connected to the top of said first member and having an outer surface generally configured in the shape of a cylinder and having an outer diameter approximately equal to the top portion of said first member and being inserted into a canalis tarsi region of the patient's sinus tarsi; . . .

27. The "second member" element of Claim 1 corresponds to the Vilex implant as shown in Exhibit B, panel 2, reproduced below:



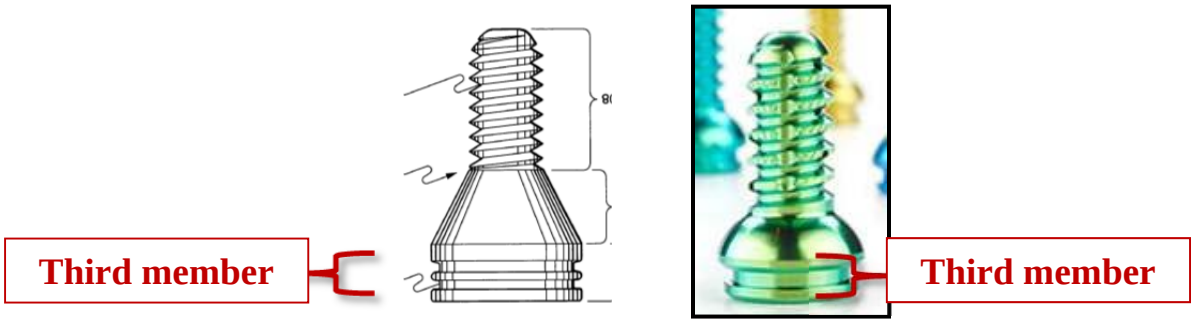


U.S. Pat. 7,033,398, Fig. 4 Vilex infringing implant. Ex. B

28. The next element of Claim 1 is the implant's "third member:"

> . . .and a third member, axially connected to the base of said first member and having an outer surface generally configured in the shape of a cylinder and being inserted into the sinus region of the patient's sinus

29. The "third member" element of Claim 1 corresponds to the Vilex implant as shown in Exhibit B, panel 2, reproduced below:



U.S. Pat. 7,033,398, Fig. 4 Vilex infringing implant. Ex. B

30. The final portion of Claim 1 describes how the claimed method works:

> . . .wherein said first, second and third members maintain said sinus tarsi in an anatomically correct alignment and minimize a tendency for abnormal motion between the patent's talus and calcaneus thereby correcting deformities in the patient's ankle bond structure.

31. The Vilex implant is placed in exactly the same location in a patient's ankle as the implant defined in Claim 1, the sinus tarsi, and is surgically implanted and functions in precisely the same way, as recited in Claim 1.

COUNT II: INFRINGEMENT OF CLAIM 2 OF U.S. PATENT NO. 7,033,398

32. Graham restates the allegations of paragraphs 1 through 31 above as if fully set forth herein.

33. Claim 2 begins:

> A method of correcting anatomical alignment of a patient's ankle bone structure as defined in claim 1 . .

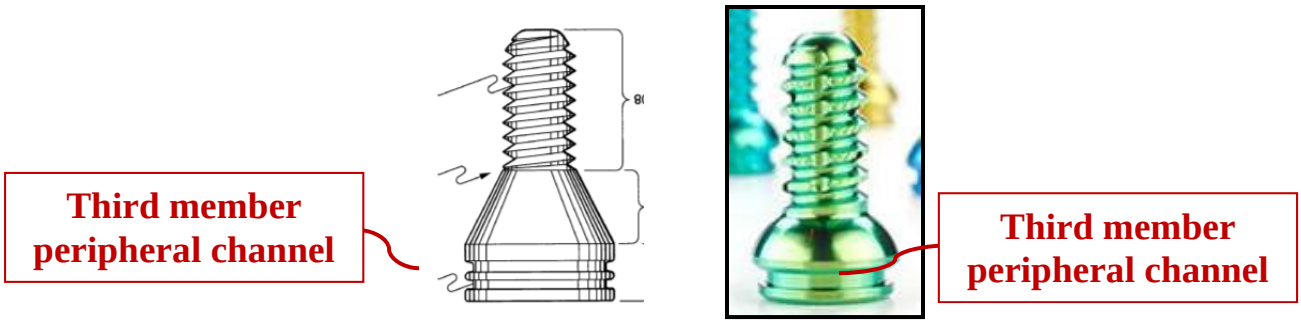
34. Claim 2 is a dependent claim. It depends from Claim 1 and thus incorporates all the elements of Claim 1.

35. The elements of Claim 2 that are incorporated from Claim 1 are infringed as set forth in Count I above.

36. The next portion of Claim 2 is:

> . . . wherein said third member further comprises:
> at least one peripheral channel fashioned about said third member outer surface to engage surrounding tissue and permit fibrous tissue ingrowth to anchor said implant within the patient's sinus tarsi.

37. This element of Claim 2 corresponds to the Vilex implant as shown in Exhibit B and illustrated below:



U.S. Pat. 7,033,398, Fig. 4 Vilex infringing implant. Ex. B

COUNT III: INFRINGEMENT OF CLAIM 3 OF U.S. PATENT NO. 7,033,398

38. Graham restates the allegations of paragraphs 1 through 37 above as if fully set forth herein.

39. Claim 3 begins:

> A method of correcting anatomical alignment of a patient's ankle bone structure as defined in claim 1 . . .

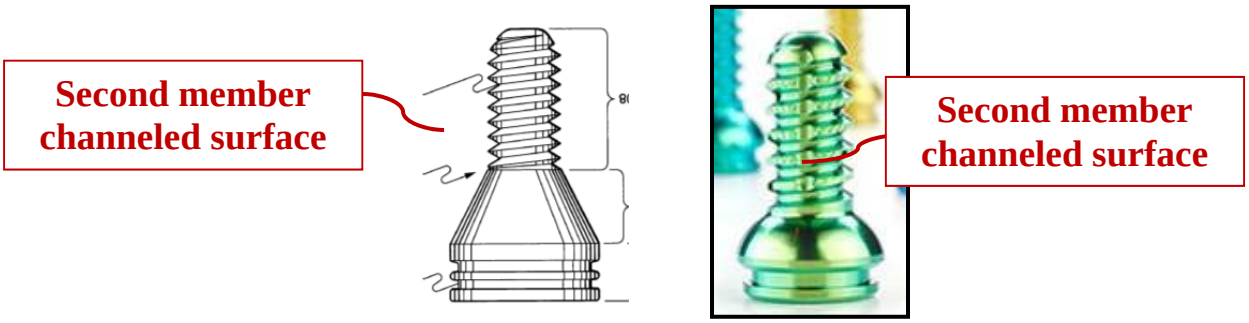
40. Claim 3 is a dependent claim. It depends from Claim 1 and thus incorporates all the elements of Claim 1.

41. The elements of Claim 3 that are incorporated from Claim 1 are infringed as set forth in Count I.

42. The next portion of Claim 3 is:

> . . . wherein said second member further comprises:
> a channeled surface fashioned in said second member outer surface to engage surrounding tissue and permit fibrous tissue ingrowth to anchor said second member within the canalis tarsi region of the patient's sinus

43. This element of Claim 3 corresponds to the Vilex implant as shown in Exhibit B and illustrated below:



U.S. Pat. 7,033,398, Fig. 4 Vilex infringing implant. Ex. B

COUNT IV: INFRINGEMENT OF CLAIM 4 OF U.S. PATENT NO. 7,033,398

44. Graham restates the allegations of paragraphs 1 through 43 above as if fully set forth herein.

45. Claim 4 begins:

> A method of correcting anatomical alignment of a patient's ankle bone structure as defined in claim 3 . . .

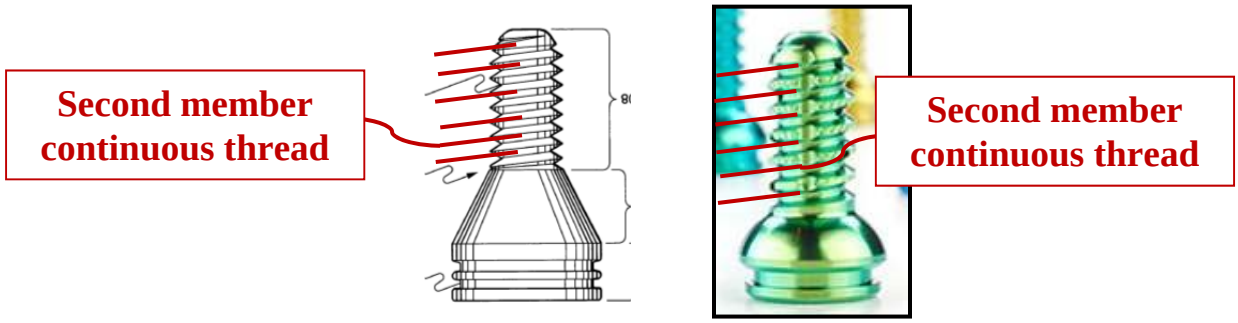
46. Claim 4 is a dependent claim. It depends from Claim 3 and thus incorporates all the elements of Claim 3.

47. The elements of Claim 4 that are incorporated from Claim 3 are infringed as set forth in Counts I - III.

48. The next portion of Claim 4 is:

> . . . wherein said channeled surface further comprises:
> a continuous thread fashioned in said second member outer surface to engage surrounding tissue and permit fibrous tissue ingrowth to anchor said second member within the canalis tarsi region of the patient's sinus

49. This element of Claim 4 corresponds to the Vilex implant as shown in Exhibit B and illustrated below:



U.S. Pat. 7,033,398, Fig. 4 Vilex infringing implant. Ex. B

COUNT V: INFRINGEMENT OF CLAIM 5 OF U.S. PATENT NO. 7,033,398

50. Graham restates the allegations of paragraphs 1 through 49 above as if fully set forth herein.

51. Claim 5 begins:

> A method of correcting anatomical alignment of a patient's ankle bone structure as defined in claim 4 . . .

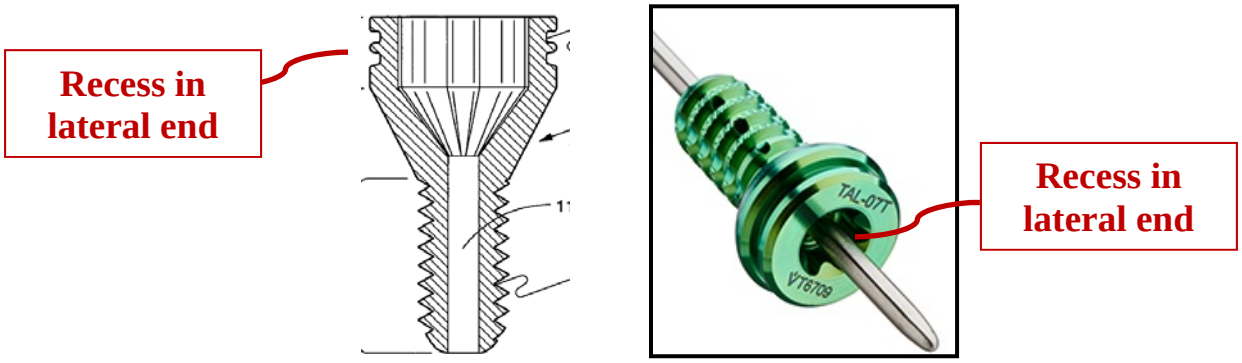
52. Claim 5 is a dependent claim. It depends from Claim 4 and thus incorporates all the elements of Claim 4.

53. The elements of Claim 5 that are incorporated from Claim 4 are infringed as set forth in Counts I - IV.

54. The next portion of Claim 5 is:

> . . . wherein said implant further comprises:
> a recess fashioned within a lateral end of said implant and being configured to accept a tool so that when the tool is inserted into the recess the tool is operable to advance the implant into a proper position.

55. This element of Claim 5 corresponds to the recess in the Vilex implant as shown in Exhibit B, panel 1, illustrated below:



U.S. Pat. 7,033,398, Fig 6 Vilex implant Exhibit B, panel 1

56. The "recess" element of Claim 5 is designed for use with the Vilex tool, Exhibit B, panel 4, pictured below, which is inserted into the recess to advance the Vilex implant into a proper position.

COUNT VI: INFRINGEMENT OF CLAIM 8 OF U.S. PATENT NO. 7,033,398

57. Graham restates the allegations of paragraphs 1 through 56 above as if fully set forth herein.

58. Claim 8 begins:

> A method of correcting anatomical alignment of a patient's ankle bone structure as defined in claim 1 . . .

59. Claim 8 is a dependent claim. It depends from Claim 1 and thus incorporates all the elements of Claim 1.

60. The elements of Claim 8 that are incorporated from Claim 1 are infringed as set forth in Count I.

61. The next portion of Claim 8 is:

> . . . and further comprising: a longitudinal bore traversing the entire length of the implant along the implant longitudinal central axis and fashioned to allow placement of the implant on a guide to facilitate proper surgical implantation..

62. This element of Claim 8 corresponds to the "cannulation" in the Vilex implant as shown in Exhibit B, panel 1, illustrated below:

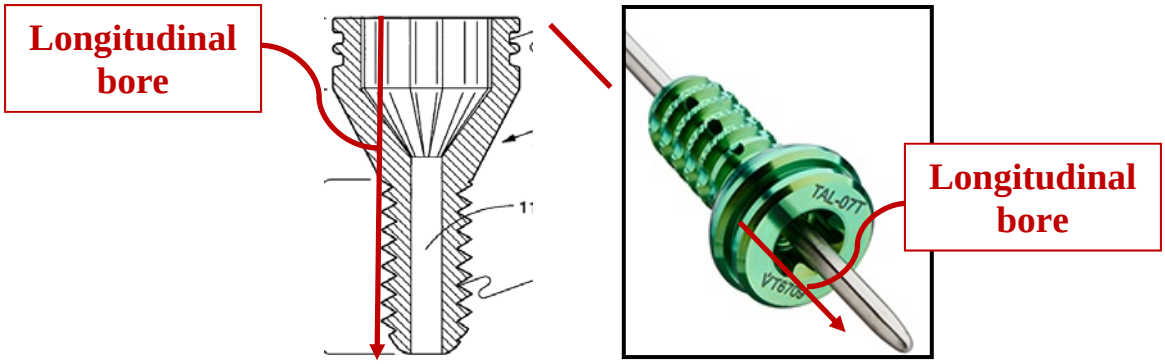


Figure 6, Graham Patent Vilex infringing implant, Exhibit b, panel 1

63. The longitudinal bore is further described in Exhibit B, panel 3, as "cannulated titanium implant for precise positioning."

INDUCED ACTS OF INFRINGEMENT 35 USC 271 (b).

64. Defendants have infringed and continue to infringe U.S. Pat. No. 7,033,398, pursuant to 35 U.S.C. §§ 271(a), (b), (c) and/or (g), either directly or indirectly, literally or under the doctrine of equivalents, by making, using, offering for sale and selling in the United States, without authority, the Vilex treatment for subtalar joint hyperpronation.

65. Vilex knew of the Graham Patent after the Graham Patent Application, No. 2005/0187636, was discussed by the patent examiner during prosecution of a Vilex patent, No. 8,628,582 (for a competing implant) and the Graham application was cited on the face of the Vilex patent.

66. Vilex knew of Graham Patent shortly after products and methods associated with the Graham Patent where introduced and gained recognition in the

orthopedic and podiatric industry for which Vilex supplies products as a competitor of Graham. On information and belief, Vilex investigated the Graham products and methods and knew of the Graham Patent at least as result of its investigation.

67. Vilex knew of the Graham Patent when Vilex had a duty with respect to its TALEX implant, an FDA class II medical device, to learn of the Graham Patent associated devices and methods. Under the FDA 510(k) approval process for class II medical devices, Vilex must compare its device to legally marketed predicate devices, specifically the Graham Patent associated devices and methods.

68. Surgeons throughout the U.S. directly infringe the Graham Patent when they follow the directions supplied by Vilex and insert the TALEX device into patients.

69. Vilex actively induces infringement by these surgeons when Vilex supplies the TALEX device and the instruction to these surgeons.

70. Defendants' infringing activities have caused and will continue to cause Graham irreparable harm, for which he has no adequate remedy at law, unless Defendants' infringing activities are enjoined by this Court in accordance with 35 U.S.C. § 283.

71. Graham has been and continues to be damaged by Defendants' infringement of the Patent in an amount to be determined at trial.

72. On information and belief, Defendants' infringement of the Patent is willful and deliberate, and justifies an increase in damages of up to three times in accordance with 35 U.S.C. § 284.

73. On information and belief, Defendants' infringement of the Patent is exceptional and entitles Graham to attorneys' fees and costs incurred in prosecuting this action in accordance with 35 U.S.C. § 285.

VILEX'S DECEPTIVE ADVERTISING AND UNFAIR COMPETITION

74. Graham restates the allegations of paragraphs 1 through 73 and above as if fully set forth herein.

75. The TALEX implant is an FDA designated class II medical device and, accordingly, Vilex must seek approval from the FDA under the 510(k) premarket notification process before it can be sold to the public.

76. On information and belief, Vilex has not submitted the TALEX implant to the FDA for approval and the FDA has not approved the TALEX implant.

77. Vilex advertises its TALEX implant on a Vilex webpage which contains a link to the FDA 510(k) premarket notification database, a government resource in which the public can verify whether certain medical devices have been approved by the FDA.

78. The link on the TALEX webpage deceptively leads the public to believe the TALEX device has been approved by the FDA. The link takes the public to the FDA database record for the Talus of Vilex (ToV) implant, not the TALEX implant.

79. The Vilex ToV implant is a separate and distinct implant from the Vilex TALEX implant.

80. The ToV implant has been approved by the FDA, but the TALEX implant has not.

81. Vilex also deceptively leads the public to believe the TALEX implant is FDA approval by added the name "TALEX" to the FDA database record for the ToV implant.

COUNT VII
FALSE ADVERTISING - FEDERAL UNFAIR COMPETITION

82. Plaintiff restates the allegations contained in paragraphs 1 - 81 as if fully set forth herein.

83. Defendants' actions as described above constitute false advertising, specifically, a misleading description/representation of fact, under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

84. On information and belief, Defendants' know that the unlawful conduct described above is commercial advertising, or promotion, that is likely to deceive the public as to the approval of Defendants' goods by the FDA. The

actions by the Defendants is therefore deliberate and done for the purpose of misleading consumers.

85. Defendants' false advertising directly damages Plaintiff because sales to Defendant's are sales lost by Plaintiff.

86. Defendant's actions also damage Plaintiff's reputation with the public and with its medical device distributors. Plaintiff sought, and received, FDA approval before publically marketing the device. This has furthered Plaintiff's reputation as an ethical medical manufacturer, in general, and specifically as concerned for public safety. Defendants' non-approved device is currently being implanted into members of the public. As a result, Plaintiff is currently at risk for loss of reputation should it become common knowledge that Defendants' device, which looks like Plaintiff's device, is not FDA approved. The loss of reputation will be devastating should any patient be harmed due to flaws in Defendants' look-alike device that Defendants failed to uncover when it disregarded the FDA approval process.

87. Defendants' false advertising involves such circumstances that damages should be increased by three times actual damages, as well as include an award for reasonable attorneys' fees and costs under 15 U.S.C. § 1117.

88. Plaintiff has no adequate remedy at law. Defendants' false advertising will likely continue unless enjoined by this Court.

89. Plaintiff requests a preliminary, and thereafter permanent, injunction against the Defendants, as well as all other remedies available under the Lanham Act, including but not limited to compensatory damages, treble damages, disgorgement of profits, costs and attorney's fees, and any other relief the Court deems appropriate.

COUNT VIII
UNFAIR COMPETITION UNDER FEDERAL LAW

90. Plaintiff restates the allegations in paragraphs 1-89 as if fully set forth herein.

91. As a result of the actions described above, Defendants' know that their actions are likely to deceive the public and cause confusion as to the approval of defendants' goods by the FDA and are deliberate and done for the purpose of misleading consumers, and are actionable under 15 U.S.C. § 1125(a) for Federal and common law unfair competition.

92. Defendants' unfair competition directly damages Plaintiff because Plaintiff and Defendants are competitors and sales to Defendants are sales lost by Plaintiff.

93. Defendants' unfair competitive actions damages Plaintiff's reputation with the public because Plaintiff is currently at risk for loss of reputation should it become common knowledge that Defendants' device, which looks like Plaintiff's device, is not FDA approved and should any patient be harmed due to flaws in

Defendants' look-alike device that Defendants failed to uncover when it disregarded the FDA approval process.

94. Plaintiff has no adequate remedy at law. Defendants' unfair competition will likely continue unless enjoined by this Court.

95. Plaintiff requests a preliminary, and thereafter permanent, injunction against the Defendants, including but not limited to compensatory damages, disgorgement of profits, costs and attorney's fees, and any other relief the Court deems appropriate.

COUNT XI
VIOLATIONS OF THE MICHIGAN CONSUMERS PROTECTION ACT

96. Plaintiff incorporates the allegations contained in paragraphs 1-95 as if fully set forth herein.

97. Defendants' acts as described above constitute violations of Michigan's Consumer Protection Act, M.C.L.A. § 455.901 et seq. at least because the acts are unfair, unconscionable, or deceptive:

a. under § 3(1)(a) of the Act, M.C.L.A. § 445.903, for causing a probability of confusion as to FDA approval of the TALEX device,

b. under § 3(1)(c) for falsely representing that the TALEX device has FDA approval, and/or

c. under § 3(1)(s) for failing to reveal the material fact that the TALEX device is not FDA approved.

98. Defendants' acts were done knowingly and willfully and both the Plaintiff and the public have been injured by such acts.

99. Defendants' acts are the proximate cause of such injury and damage.

100. Defendants' acts will likely continue unless enjoined by this Court.

101. Plaintiff requests a preliminary, and thereafter permanent, injunction ordering Defendant to stop all marketing of the TALEX device, as well as damages in an amount to be determined at trial, along with reasonable attorney's fees, costs, exemplary damages, and any other relief that the Court deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Graham demands a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Graham, respectfully prays for relief as follows:

(a) A preliminary, and thereafter permanent, injunction enjoining Defendant Vilex in Tennessee and its officers, directors, agents, servants, employees, affiliates, attorneys, and all others acting in privity or in concert with them, and their parents, subsidiaries, divisions, successors and assigns, from further acts of infringement, contributory infringement, or inducement of infringement of the Patent;

(b) A judgment that Defendants have induced infringement of one or more claims of the Patent;

(c) A judgment that Defendants have willfully and intentionally made false and deceptive statements with respect to Defendants' goods in violation of Section 1125(a) of the Lanham Act and in violation of Michigan Consumers Protection Act.

(d) A judgment awarding Graham all damages adequate to compensate for Defendants' infringement, and in no event less than a reasonable royalty for Defendants' acts of infringement, including all pre-judgment and post-judgment interest at the maximum rate permitted by law;

(e) A judgment that Defendants' various acts of infringement have been willful and deliberate, and therefore, that Graham is entitled to up to treble damages as provided by 35 U.S.C. § 284;

(f) A judgment awarding Graham all gains, profits and advantages derived from Defendants' false and deceptive statements and that Defendants' various false and deceptive statements were willful and deliberate and therefore, that Graham is entitled to up to treble damages as provided by 15 U.S.C. § 1117(a).

(g) A judgment that Defendants' acts render this an exceptional case entitling Graham to an award of its attorneys' fees and costs incurred in

prosecuting this action, together with interest, pursuant to 35 U.S.C. § 285, 15 U.S.C. § 1117(a) and under § 11 of the Michigan Consumers Protection Act, M.C.L.A. § 455.911.

(h) An Order directing Defendant Vilex in Tennessee and its officers, directors, agents, servants, employees, affiliates, attorneys, and all others acting in privity or in concert with them, and their parents, subsidiaries, divisions, successors and assigns, to immediately remove all mentions of the VILEX device and any other marks confusingly similar from all aspects of its business, including but not limited to websites, television stations, publications, social media, newsletters, and/or any other media.

(i) Such other and further relief as the Court shall deem just and proper.

Dated: September 24, 2015

Respectfully Submitted,

/s/ John A. Artz

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