**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**EL PASO DIVISION**

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| MEDICAL COMPONENTS, INC. and MARTECH MEDICAL PRODUCTS, INC., | ) | |
| Plaintiffs, | ) | Civil Action No. 3:15-cv-00305-PRM |
| vs. | ) | |
| OSIRIS MEDICAL, INC., and, RAUL GARCIA, JR., | ) | |
| Defendants. | ) | |

**SECOND AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 7,125,398**

Plaintiffs Medical Components, Inc. ("MedComp") and Martech Medical Products, Inc. ("Martech") (collectively, "Plaintiffs"), for their complaint against Defendants Osiris Medical, Inc. ("Osiris"), and Raul Garcia, Jr. ("Garcia" and, together with Osiris, "Defendants") allege as follows:

**NATURE OF THE ACTION**

1. This is an action seeking a declaratory judgment that Plaintiffs do not infringe any claim of U.S. Patent No. 7,125,398 ("the '398 patent"), a copy of which is attached hereto as Exhibit A. Garcia purports to be the owner/holder of the '398 patent.

2. As such, this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the patent laws of the United States, 35 U.S.C. § 100, *et seq*.

## THE PARTIES

3. Plaintiff Medical Components, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 1499 Delp Drive, Harleysville, Pennsylvania 19438.

4. Plaintiff Martech Medical Products, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 1500 Delp Drive, Harleysville, Pennsylvania 19438.

5. Upon information and belief, Defendant Osiris Medical, Inc., is a company organized and existing under the laws of the State of Delaware, having a registered address of 10608 Tiber Place, El Paso, Texas 79924.

6. Garcia is an adult individual who, upon information and belief, resides at 10708 McAllen Place, El Paso, Texas 19924. Upon further information and belief, he is the President of Osiris. As noted above, Garcia purports to be the owner/holder of the '398 patent.

## JURISDICTION AND VENUE

7. This is an action seeking a declaratory judgment under 28 U.S.C. §§ 2201-02.

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq*.

9. Defendants are subject to general and specific personal jurisdiction in this judicial district based on their purposeful, systematic, and continuous contacts

with this state, including having a place of business and a residence in El Paso, Texas.

10. Venue is proper in this judicial district under 28 U.S.C. § 1391, because Defendants are subject to personal jurisdiction in this district, reside in this district, and/or transact affairs in this district, including having a place of business and residence in El Paso, Texas.

## BACKGROUND

11. The '398 patent is entitled "Medical Needle Guard," lists Raul Garcia, Jr. on its face as the sole inventor, and issued on October 24, 2006 from an application filed April 30, 2003.

12. MedComp and Osiris were parties to a patent licensing agreement ("PLA"), purporting to convey a license to make, have made, use, offer to sell, sell, and import products under the '398 patent from Osiris to MedComp. A copy of the PLA is attached hereto as Exhibit B.

13. The PLA was executed by Osiris and MedComp on December 19 and 20, 2011, respectively (Ex. B at 10), and was for a stated period of three years. *Id.* at ¶ 9(a). As such, by its terms, the PLA expired no later than December 20, 2014.

14. The PLA recited a grant of a non-exclusive, non-assignable license to the '398 patent for the purpose of manufacturing, advertising, and selling certain "Product" in the U.S. and abroad, upon certain terms and conditions. *Id.* at ¶ 3(a).

15. The PLA defined "Product" as follows:

> "Product" shall encompass the needle guard to be manufactured under this License by Licensee or

> Licensee's manufacturer, arising under the medical needle guard as described in the Patent and the product design known as the Huber Safety Infusion Set provided to Licensee by Licensor. Product only includes devices that would infringe the Patent.

*Id*. at ¶ 1(d).

16. The PLA also contained a section entitled "New Product," the first subsection of which read as follows:

> If and when Licensee applies for and receives FDA approval for a CT Huber 510k product during the Term of this Agreement, then such product shall be considered to be a "Product" for purposes of this Agreement during its Term so long as such product to be manufactured would infringe any claim of the Patent.

*Id*. at ¶ 8(a).

17. MedComp initially attempted to contract with a third-party vendor recommended by Garcia called Integra, located in California and Mexico to have a first CT Huber needle product (the "V1" product) manufactured. This was an arrangement contemplated and facilitated by Osiris and V1 fell under the PLA. However, this manufacturing attempt by Integra proved unsuccessful, and MedComp was unable to obtain a commercially-saleable version of V1 because Integra was unable to meet quality and performance standards for the product.

18. MedComp then engaged Martech, a contract Original Equipment Manufacturer (OEM), to attempt to make the V1 product under an assumed sublicense from MedComp under the PLA.

19. However, by the time Martech was able to make the V1 product only a few months remained under the PLA.

20. Due to the nature of the medical device industry, the relevant patent rights needed to be assured for a substantial amount of time in order to guarantee supply and convince market participants to switch over to using the V1 product, in addition to justifying the expense relating to tooling and production for commercial-scale manufacture. Because only 3 months of rights could be secured and assured under the PLA and Osiris's demand for increased royalties to extend the PLA, the V1 product could not be economically pursued.

21. Aside from the V1 product, MedComp contracted with Martech to design and develop a new and different CT Huber needle product for MedComp ("the MedComp product"), with new inventive features not found in the '398 patent or covered under the PLA.

22. MedComp and Martech have developed and made three new versions of the MedComp product, referred to as V2, V3 and V4, which have new inventive elements that are not found in and do not infringe the '398 patent, which are different from the inventive elements in the V1 design and do not fall under the PLA.

23. After the expiration of the PLA, Osiris (through counsel) sent MedComp a letter dated July 8, 2015, a copy of which is attached as Exhibit C. In that letter, Osiris asserted that it was owed a certain sum of money pursuant to the PLA, and further asserted its entitlement to "be compensated for any new product development pursuant to paragraph 8" of the PLA. Ex. C at 1.

24. In the July 8, 2015 letter, Osiris also demanded a "full audit and disclosure of the financial books and records of MedComp regarding its sales of the CT Huber, it's [sic] efforts to obtain FDA 510k approval [sic] this product and any new products derived from the efforts of Garcia, in whole or in part." *Id.*

25. In a telephone conversation on September 30, 2015, Garcia accused MedComp of infringing the '398 patent.

26. On October 13, 2015, Garcia conducted an "audit" of certain categories of MedComp documents, as requested. At this audit, Garcia once again accused MedComp or infringing the '398 patent.

27. Because patent infringement is a strict liability offense, Defendants' allegations of patent infringement against Medcomp necessarily also expose Martech (and all others along the chain of commerce) to liability related to Defendants' allegations.

**COUNT I**

**(Declaratory Judgment for Non-Infringement of U.S. Patent No. 7,125,398)**

28. Plaintiffs incorporate and re-allege the allegations set forth in the preceding paragraphs as though fully stated herein.

29. To satisfy the case or controversy requirement for declaratory judgment jurisdiction, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S.

118, 127 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

30. In the patent context, declaratory judgment jurisdiction exists "where [1] a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and [2] where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

31. Through their communications and actions, Defendants have asserted rights under the '398 patent based on Plaintiffs' ongoing or planned activity with respect to the MedComp product, including Medcomp's own proprietary versions V2, V3 and V4, and have accused Plaintiffs of infringing the claims of the '398 patent.

32. Further, through their accusations that MedComp and/or Martech have developed and/or sold a new "Product" as defined in the PLA, Defendants have effectively charged MedComp and Martech of infringing the claims of the '398 patent.

33. Plaintiffs contend that they have the right to make, use, sell, offer for sale and import the MedComp product, including versions V2, V3 and V4, without a license from Defendants, because the MedComp product does not infringe any claims of the '398 patent.

34. MedComp does not now nor has it ever infringed any valid claim of the '398 patent, directly or indirectly. MedComp has not contributed to nor induced infringement of the '398 patent. MedComp denies any and all claims of liability for alleged patent infringement.

35. Martech does not now nor has it ever infringed any valid claim of the '398 patent, directly or indirectly. Martech has not contributed to nor induced infringement of the '398 patent. Martech denies any and all claims of liability for alleged patent infringement.

36. The '398 patent contains 16 patent claims, of which 1, 2, 14 and 16 are independent claims.

37. Claim 1 of the '398 patent recites: "A needle guard comprising: a base having a needle well; a handle attached to the base by a connector, and a needle holder capable of securing a medical needle having a pointed end, wherein the extent to which the base can be moved away from the handle is limited by the connector, and the walls of the needle well completely surrounds the needle point when the handle is distally extended away from the base, and wherein the connector is structured so that the handle is capable of being pushed towards the base such that the needle is guided beyond the needle well, said needle guard further comprising a cover attachable to said base capable of covering said needle well when the needle point is in the well." Ex. A, col. 5, l. 57 - col. 6, l. 6.

38. The MedComp product, including V2, V3 and V4, does not directly infringe claim 1 of the '398 patent, either literally or under the doctrine of

equivalents, because *inter alia*, the MedComp product does not include a connector and/or a cover as recited in claim 1.

39. Claim 2 of the '398 patent recites: "A needle guard for a medical needle having a portion with a pointed end adapted for insertion into a patient, said needle guard comprising: a base having a needle well; a handle attached to the base, said base and handle being connected by a connector, and a needle holder capable of securing a medical needle having a pointed end, wherein movement of the base toward or away from said handle is limited by said connector, and said needle well completely surrounds and covers the needle point when the handle is distally extended away from said base and when said needle point is in said well, and wherein said connector is structured so that said handle is capable of being pushed towards said base to guide said point of said needle into said well and through said base, said connector comprising connected accordion walls which are locked together when in extended position and which fold toward one another when said handle is pushed towards said base to move said needle into said well, said needle at all times being covered by said needle guard except for the portion inserted in a patient." Ex. A, col. 6, ll. 7-31.

40. The MedComp product, including V2, V3 and V4, does not directly infringe claim 2 of the '398 patent, either literally or under the doctrine of equivalents, because *inter alia*, the MedComp product does not include a connector and/or a cover as recited in claim 2; in the MedComp product the movement of the upper portion toward the lower portion is not limited by the connector; upper

portions of the MedComp product are not pushed toward the base during use of the MedComp product; in the MedComp product the needle point is not guided into the well; and in the MedComp product the needle is not at all times being covered by the needle guard except for the portion inserted into the patient.

41. Claims 3-13 depend directly or indirectly from claim 2, and as such the MedComp product, including V2, V3 and V4, does not infringe any of claims 3-13, literally or under the doctrine of equivalents, for at least the same reasons that claim 2 is not infringed.

42. Claim 16 of the '398 patent recites: "A needle guard for a medical needle intended for use to prevent unintended needle sticks, said needle having a pointed end adapted for insertion into a patient at a time of use, said needle guard comprising: a base having a needle well; a handle attached to the base, said base and handle being connected by a connector, and a needle holder capable of securing a medical needle having a pointed end, wherein movement of the base toward or away from said handle is limited by said connector, and said needle well completely surrounds and covers the needle point when the handle is distally extended away from said base and when said needle point is in said well, and wherein said connector is structured so that said handle is capable of being pushed towards said base to guide said point of said needle into said well and through said base, said connector comprising connected walls which are locked together when in extended position and which move together when said handle is pushed towards said base to move said needle into said well, said needle at all times while in said guard, before,

during and after insertion, being shielded from unintended needle sticks." Ex. A, col. 8, ll. 4-31.

43. The MedComp product, including V2, V3 and V4, does not directly infringe claim 16 of the '398 patent, either literally or under the doctrine of equivalents, because *inter alia*, the MedComp product does not include a connector as recited in claim 16; upper portions of the MedComp product are not pushed toward the base during use of the MedComp product; in the MedComp product the needle point is not guided into the well; the MedComp product does not have connected walls which are locked together; and in the MedComp product the needle is not shielded at all times.

44. Claim 14 of the '398 patent recites: "A method of using a medical needle having a pointed end comprising: providing a needle guard having a base comprising a needle well, a handle attached to the base by a foldable connector, a locking means that, when locked, is capable of keeping the handle and the base at distal ends of the connector, a needle holder securing the needle to the guard, wherein the handle is initially extended away from the base, such that a pointed end of the needle is surrounded by the walls of the needle well; placing the needle guard substantially against a patient so that the needle well is above an area for the needle to be inserted; folding the connector against the base by pressing the handle towards the base thus inserting the needle into the patient; pulling the handle away from the base to unfold the connector and retract the needle from the patient, such that the connectors directs the pointed end back within the needle

well; locking the locking means, and maintaining the needle fully covered at all time except for the portion inserted into the patient." Ex. A, col. 7, l. 8 to col. 8, l. 3.

45. The MedComp product, including V2, V3 and V4, does not directly infringe claim 14 of the '398 patent, either literally or under the doctrine of equivalents, because the MedComp product is a product and not a method.

46. The MedComp product, including V2, V3 and V4, also does not directly infringe claim 14 of the '398 patent, either literally or under the doctrine of equivalents, because *inter alia*, the MedComp product does not include a locking means as recited in claim 14; use of the MedComp product does not involve the upper portion being extended away from the base; use of the MedComp product does not involve placing the needle guard substantially against a patient so that the needle well is above an area for the needle to be inserted; use of the MedComp product does not involve folding the connector against the base by pressing the handle towards the base thus inserting the needle into the patient; use of the MedComp product does not involve maintaining the needle fully covered at all time except for the portion inserted into the patient.

47. Claims 15 depends directly from claim 14, and as such the MedComp product, including V2, V3 and V4, does not infringe claim 15, literally or under the doctrine of equivalents, for at least the same reasons that claim 14 is not infringed.

48. The MedComp product, including V2, V3 and V4, does not indirectly infringe any of claims 1-16 of the '398 patent, because the MedComp product and the use thereof does not directly infringe those claims.

49. The MedComp product, including V2, V3 and V4, does not contribute to the infringement of claims 1-13 and 16 of the '398 patent because it is not a component of any patented machine recited in those claims, does not constitute a material part thereof, and is not especially made or especially adapted for use in an infringement of claims 1-13 and 16.

50. The MedComp product, including V2, V3 and V4, does not contribute to the infringement of claims 14 and 15 of the '398 patent, because the MedComp product is not an apparatus for use in practicing the process recited in claims 14 and 15, does not constitute a material part thereof, and is not especially made or especially adapted for use in an infringement of claims 14 and 15.

51. The MedComp product, including V2, V3 and V4, does not induce the infringement of claims 1-16 of the '398 patent because there is no direct infringement of those claims, and also because Plaintiffs do not know of or intend the infringement of those claims.

52. In addition to having designed and made the MedComp product, including V2, V3 and V4, Plaintiffs have undertaken meaningful preparation for making and using the product, including fabricating the parts for the MedComp product, building up the parts required for testing, preparing the eventual submission of pre-marketing regulatory approval of the MedComp product, and fabricating prototypes.

53. V2, V3 and V4 of the MedComp product are related version of said product, V3 and V4 are improvements on V2, and all three versions share design features in common.

54. Defendants have accused MedComp of infringing the claims of the '398 patent and offering infringing products for sale to customers.

55. Plaintiffs contend that they do not infringe said patent and do not require a license, thereby creating adverse legal interests between Plaintiffs and Defendants.

56. The issue of (non)infringement of the '398 patent represents a substantial controversy between Defendants and Plaintiffs.

57. Defendants' accusations have placed MedComp and/or Martech in reasonable risk and apprehension of a lawsuit.

58. Based on the course of conduct and relationship between the parties, the adverse legal interests between Defendants and Plaintiffs are of sufficient immediacy and reality to warrant the issuance of a declaratory judgment by this Court.

59. Pursuant to 28 U.S.C. §§ 2201 and 2202, a declaratory judgment is necessary to confirm that MedComp and/or Martech do not infringe, directly or indirectly, any claim of the '398 patent.

60. Defendants' actions are ongoing and continue to inflict irreparable harm upon MedComp and/or Martech for which there exists no adequate remedy at law.

61. As such, MedComp and Martech request that this Court enter an order declaring that neither MedComp nor Martech has ever infringed any claim of the '398 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs MedComp and Martech respectfully request that judgment be entered in their favor, and pray that the Court grant the following relief:

A. A declaration that neither MedComp nor Martech infringes, either directly or indirectly, any valid and enforceable claim of the '398 patent, either literally or under the doctrine of equivalents;

B. A declaration that Garcia, Osiris, and its officers, agents, employees, representatives, counsel, and all persons in active concert or participation with any of them, directly or indirectly, be enjoined from threatening or charging infringement of, or instituting or continuing any action for infringement of the '398 patent against MedComp and/or Martech;

C. A declaration that this is an exceptional case under 35 U.S.C. § 285;

D. Awarding Plaintiffs their costs, expenses, and reasonable attorneys' fees, and pre- and post-judgment interest on any money judgment; and

E. Granting such other and further relief as this Court deems just and proper.

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs hereby demand a trial by jury on all issues and claims to triable.

Dated: July 22, 2016

Respectfully submitted,

*/s/ Alfred Zaher*

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**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on July 22, 2016, true and correct copies of the foregoing were served, upon the individuals listed below, in the following manner:

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