UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA FORT MYERS DIVISION

GIAN BIOLOGICS, LLC, a Delaware Limited Liability Corporation,

Plaintiff,

v.

Case No. 2:15-cv-645-FtM-99CM

CELLMEDIX HOLDINGS, LLC, a New Jersey Limited Liability Company; PERFUSION.COM, INC., a Florida Corporation; NORTH AMERICAN STERILIZATION AND PACKAGING COMPANY, INC., a New Jersey Corporation; BRYAN V. LICH, an individual Florida Resident; and, PAUL WIEBEL JR., an individual New Jersey Resident,

Defendants.

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[PROPOSED] AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL AND INJUNCTIVE RELIEF SOUGHT

Plaintiff, Gian Biologics, LLC ("Gian"), sues CellMedix Holdings, LLC ("CellMedix"), Perfusion.com, Inc. ("Perfusion"), North American Sterilization and Packaging Company, Inc. ("NASP), Bryan V. Lich, and Paul Wiebel Jr. (also known as, "P.J. Wiebel") (collectively, "Defendants") for patent infringement and alleges:

PARTIES

 Gian is a limited liability corporation organized and existing under the laws of Delaware, and maintains its principal place of business at 13881 Plantation Road, Suite 2, Fort Myers, Florida 33912. Among other things, Gian develops, improves and commercializes state-of-the-art devices used in preparing autologous platelet rich plasma from blood samples.

- CellMedix is a limited liability corporation organized and existing under the laws of the State of New Jersey and maintains a place of business at 19 Park Drive, Franklin, New Jersey 07416.
- Perfusion is a corporation organized and existing under the laws of the State of Florida and maintains its principal place of business at 17080 Safety St., Suite 109, Fort Myers, Florida, 33908.
- 4. NASP is a corporation organized and existing under the laws of the State of New Jersey and maintains a place of business at 19 Park Drive, Franklin, New Jersey 07416, which is the same location where CellMedix does business.
- 5. Bryan V. Lich is an individual residing in the State of Florida. He is the President of Defendant CellMedix and Defendant Perfusion. In addition, he is a co-owner of Defendant Perfusion. Bryan V. Lich is also a co-owner of CellMedix, Inc., a Florida corporation that has a 49% ownership interest in Defendant CellMedix.
- 6. P.J. Wiebel is an individual residing in the State of New Jersey. He is the President and Chief Executive Officer of NASP. P.J. Wiebel is also the Chairman and Chief Executive Officer of Defendant CellMedix. In addition, he is a beneficiary of the Paul A.S. Wiebel Irrevocable Family Trust, which owns Wiebel Holding, LLC, a New Jersey limited liability corporation that has a 50% ownership interest in PJR, LLC which has a 51% ownership interest in Defendant CellMedix.

JURISDICTION AND VENUE

- Plaintiff brings this action for patent infringement under the Patent Act, 35 U.S.C. § 1 *et seq*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 15 U.S.C. § 1121(a).
- 8. Venue in this judicial district is proper pursuant to 28 U.S.C. §§ 1391 and 1400.
- Perfusion is a corporation organized and existing under the laws of the State of Florida, with its principal place of business in Fort Myers, Florida. Bryan Lich resides in Fort Myers, Florida.
- 10. The exercise of personal jurisdiction over Perfusion, CellMedix, NASP, Bryan Lich and P.J. Wiebel is proper pursuant to, *inter alia*, Florida's long-arm statute, section 48.193 (1), (2) and (9), Florida Statutes (2000). They are subject to this Court's jurisdiction at least by: using, supplying, offering for sale, or selling, whether personally or through an agent causing such activities in this judicial district, packaged products that infringe Plaintiff's patent or substantial noninfringing components of Plaintiff's patent; shipping infringing products to consumers in this judicial district; supplying or causing to be supplied in or from the United States substantial noninfringing components of any invention(s) claimed in the '353 Patent; receiving revenue from Florida residents; filing lawsuits in the courts of the State of Florida; holding licenses issued by the State of Florida; and, entering into contracts which contain provisions for the choice of the law of the State of Florida and their submission to the jurisdiction of the courts of the State of Florida.

FACTUAL BACKGROUND

United States Pat. No. 6,835,353

- 11. United States Pat. No. 6,835,353 ("the '353 Patent"), entitled "Centrifuge Tube Assembly," issued on December 28, 2004. Gian is the assignee of the '353 Patent. A true and correct copy of the '353 Patent is attached as **Exhibit A**.
- 12. The '353 Patent relates to an improved centrifuge tube assembly that allows blood to be aspirated in discrete components in a way that is more efficient and effective than conventional centrifuge tubes.

The Accused Device and Defendants' Infringing Activities

13. According to its website and related marketing materials, CellMedix manufactures and offers for sale and sells centrifuge tube assemblies, components, parts, accessories, packaging, and bundles, including without limitation: kits such as the CENTREPID PC KIT, part number CELL-80180-A (the "Centrepid PC Kit"); vials such as part number CELL-80180AA (the "Centrepid PC"); trays such as part number CELL-55090 (the "Tray"); packaging such as part number CELL-57140 (the "Packaging"); adapters such as part number CELL 80420-A (the "Adapter"); carriers or rotors such as part number CELL-80400-A (the "Rotor"); centrifuges such as part numbers CELL-FUTURE and CELL-80390-A (the "Centrifuge Kit"); buckets; and, bundles such as part number CELL-81480-A (the "Centrifuge Bundle") (collectively, the "Accused Device"). A copy of a brochure of the Accused Device obtained from the CellMedix website (www.cellmedix.com) is attached as Exhibit B. A copy of instructions for the use of the

Accused Device obtained from the CellMedix website is attached as **Exhibit C** ("Instructions for Use").

14. For example, CellMedix offers for sale and sells centrifuge tube assemblies, such as the ones depicted in Figures 1 and 2, below.



FIGURE 1

CELLMEDIX

FIGURE 2

- 15. CellMedix has offered to sell and sold the Accused Device to customers in the United States and in this judicial district.
- 16. In particular, CellMedix has offered to sell and sold the Accused Device using at least the CellMedix website at <u>www.cellmedix.com</u>.
- 17. Perfusion likewise sells and offers for sale the Accused Product. See Exhibit D.
- 18. For example, Perfusion offers for sale and sells centrifuge tube assemblies, such as the ones depicted in Figure 3, below.



FIGURE 3

- Defendants have no lawful right to make, use, offer to sell, sell or import any invention(s) disclosed and claimed in the '353 Patent.
- 20. The Defendants had knowledge of the '353 Patent at least as early as October 1, 2012 and communicated internally with each other about the '353 Patent.
- 21. Further, by way of multiple cease and desist letter, Defendants were notified that their activities constitute infringement of the '353 Patent but nevertheless refused to stop their infringing conduct. Accordingly, the Defendants' knowing use, manufacture, sale and

offer for sale of the Accused Products amounted to objectively reckless behavior. Defendants' infringement was thus willful.

- 22. Further, Defendants are attempting to shroud their infringing conduct by requiring that purchasers of the Accused Device execute non-disclosure agreements.
- 23. Upon information and belief, Bryan Lich engaged P.J. Wiebel's assistance to manufacture the Accused Device through NASP.
- 24. Upon information and belief, on or about Jan. 12, 2012, under the direction and control of Bryan Lich and P.J. Wiebel, CellMedix and NASP completed design input specification for the Centrepid PC Kit.
- 25. Upon information and belief, Bryan Lich and P.J. Wiebel caused the formation of Defendant CellMedix on May 10, 2012 in order to sell and offer for sale the Accused Device.
- 26. Upon information and belief, on or about October 1, 2012, a potential customer and distributor of Defendants expressed to Defendants serious concerns that the Centrepid PC infringed the '353 Patent. As a result, Defendants considered whether to procure a noninfringement opinion.
- 27. Upon information and belief, Defendants failed to procure a reliable or reasonable noninfringement opinion regarding Defendants' infringement of the '353 Patent.
- 28. Upon information and belief, Bryan Lich and P.J. Wiebel caused NASP to proceed to manufacture the Accused Device.
- 29. Upon information and belief, Defendants distributed, sold, offered for sale and/or caused others to do so, the following—as either separate products and in varying combinations:

the Centrepid PC, the Centrepid PC Kit, the Tray, the Packaging, the Adapter, the Rotor, the Centrifuge Kit, centrifuge buckets, the Centrifuge Bundle, and Instructions of Use.

- 30. Upon information and belief, the Centrepid PC is a material component of the invention(s) claimed in the '353 Patent. It is especially made or adapted for its use, which infringes the '353 Patent, and it is not a staple article or commodity of commerce suitable for any substantial non-infringing use. Defendants have such knowledge, by way of concerns expressed by at least one potential customer and distributor, and in light of Plaintiff's cease and desist letter.
- Upon information and belief, Defendants' distributors and customers continue to use Accused Devices.
- 32. Upon information and belief, NASP continues to manufacture, sell and offer for sale Accused Devices, to print and distribute Instructions for Use, and to induce distributors and consumers to use Accused Devices.
- 33. Upon information and belief, CellMedix and Perfusion continue to sell and offer for sale Accused Devices.
- 34. Upon information and belief, Bryan Lich and P.J. Wiebel continue to induce: NASP to manufacture Accused Devices; CellMedix and Perfusion to sell and offer for sale Accused Devices; distributors to use, sell and offer for sale Accused Devices; and, consumers to use Accused Devices.
- 35. Upon information and belief, CellMedix also continues to induce: NASP to manufacture Accused Devices; Perfusion to sell and offer for sale Accused Devices; distributors to use, sell and offer for sale Accused Devices; and, consumers to use Accused Devices.

- 36. Further, upon information and belief, Perfusion continues to induce: NASP to manufacture Accused Devices; CellMedix to sell and offer for sale Accused Devices; distributors to use, sell and offer for sale Accused Devices; and, consumers to use Accused Devices.
- 37. Upon information and belief, Defendants provided and/or caused to be provided instructions and training on the use of Accused Devices to individuals and/or entities residing aboard.
- 38. Upon information and belief, Defendants supply and/or cause to be supplied in or from the United States all or a substantial portion of the components of the invention(s) claimed in the '353 Patent, and such components—including without limitation Accused Devices and their components—are uncombined in whole or in part. Defendants supply and/or cause to be supplied such components in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '353 Patent if such combination occurred within the United States. Upon information and belief, Defendants engaged in their culpable conduct to induce and cause others to infringe the '353 Patent. Upon information and belief, Defendants have such intentions based on, *inter alias*, the instructions and training on the use of Accused Devices provided to individuals and/or entities aboard.
- 39. Upon information and belief, Defendants supply and/or cause to be supplied in or from the United States at least one component of the '353 Patent that is especially made or adapted for use in the invention(s) claimed in the '353 Patent and that is not a staple article or commodity of commerce suitable for substantial non-infringing use, and such

component—including without limitation the Centrepid PC and/or the Centrepid PC Kit—is uncombined in whole or in part. Defendants supply and/or cause to be supplied such a component with the knowledge that the component is so made or adapted and with the intention that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States. Defendants have such knowledge, by way of concerns expressed by at least one potential customer and distributor, and in light of Plaintiff's cease and desist letter. Upon information and belief, Defendants have such an intention based on, *inter alias*, the instructions and training on the use of Accused Devices provided to individuals and/or entities aboard.

COUNT I PATENT INFRINGEMENT UNDER 35 U.S.C. §271(a) BY DEFENDANTS CELLMEDIX, PERFUSION AND NASP

- 40. Plaintiff repeats the allegations set forth in paragraphs 1 through 39.
- 41. In direct violation of 35 U.S.C. § 27l(a), CellMedix has infringed one or more claims of the '353 Patent by one or more of the following infringing acts: making, selling, offering for sale, and/or using at least Accused Devices, which incorporate one or more of the inventions claimed in the '353 Patent.
- 42. The infringement by CellMedix was intentional and willful. At all relevant times, CellMedix infringed the '353 Patent with knowledge of Gian's patent rights.
- 43. Further, in direct violation of 35 U.S.C. § 271(a), Perfusion has infringed one or more claims of the '353 Patent by one or more of the following infringing acts: selling, offering

for sale, and/or using at least Accused Devices, which incorporates one or more of the inventions claimed in the '353 Patent.

- 44. The infringement by Perfusion was intentional and willful. At all relevant times, Perfusion infringed the '353 Patent with knowledge of Gian's patent rights.
- 45. In direct violation of 35 U.S.C. § 271(a), NASP has infringed one or more claims of the '353 Patent by one or more of the following infringing acts: making, selling, offering for sale, and/or using at least Accused Devices, which incorporates one or more of the inventions claimed in the '353 Patent.
- 46. The infringement by NASP was intentional and willful. At all relevant times, NASP infringed the '353 Patent with knowledge of Gian's patent rights.
- 47. As a result of Defendant CellMedix's, Defendant Perfusion's and Defendant NASP's infringing activities, Gian has sustained damages in an amount to be proven at trial.
- 48. The infringements by CellMedix, Perfusion and NASP have caused and will continue to cause Gian irreparable harm for which there is no adequate remedy at law.

COUNT II INDUCING INFRINGEMENT UNDER 35 U.S.C. §271(b)

- 49. Plaintiff repeats the allegations set forth in paragraphs 1 through 39.
- 50. CellMedix has induced NASP, Perfusion, distributors and customers to infringe one or more claims of the '353 Patent, in violation of 35 U.S.C. § 271(b).
- 51. The inducement to infringe by CellMedix was intentional and willful.
- 52. Perfusion has induced NASP, CellMedix, distributors and customers to infringe one or more claims of the '353 Patent, in violation of 35 U.S.C. § 271(b).

- 53. The inducement to infringe by Perfusion was intentional and willful.
- 54. NASP has induced distributors and customers to infringe one or more claims of the '353 Patent, in violation of 35 U.S.C. § 271(b).
- 55. The inducement to infringe by NASP was intentional and willful.
- 56. Bryan V. Lich has induced CellMedix, Perfusion, NASP, distributors and customers to infringe one or more claims of the '353 Patent, in violation of 35 U.S.C. § 271(b).
- 57. The inducement to infringe by Bryan V. Lich was intentional and willful.
- 58. P.J. Wiebel has induced CellMedix, Perfusion, NASP, distributors and customers to infringe one or more claims of the '353 Patent, in violation of 35 U.S.C. § 27l(b).
- 59. The inducement to infringe by P.J. Wiebel was intentional and willful.
- 60. As a result of Defendants' infringing activities, Gian has sustained damages in an amount to be proven at trial.
- 61. The infringements and inducements to infringe by Defendants have caused and will continue to cause Gian irreparable harm for which there is no adequate remedy at law.

COUNT III INDUCING INFRINGEMENT UNDER 35 U.S.C. §271(c) BY DEFENDANTS CELLMEDIX, PERFUSION AND NASP

- 62. Plaintiff repeats the allegations set forth in paragraphs 1 through 39.
- 63. Upon information and belief, Defendants CellMedix, Perfusion and NASP, with knowledge of Gian's rights under the '353 Patent, sold and/or offered for sale a material component of the invention(s) of the '353 Patent.
- 64. Upon information and belief, Defendants CellMedix, Perfusion and NASP had knowledge that the same component of Gian's patented invention(s) was especially made

and especially adapted for use in an infringement of the '353 Patent, and was not a staple article or commodity of commerce suitable for any substantial non-infringing use.

- 65. The contributory inducements by Defendants CellMedix, Perfusion and NASP were intentional and willful.
- 66. As a result of Defendant CellMedix's, Defendant Perfusion's and Defendant NASP's infringing activities, Gian has sustained damages in an amount to be proven at trial.
- 67. The contributory infringements by Defendants CellMedix, Perfusion and NASP have caused and will continue to cause Gian irreparable harm for which there is no adequate remedy at law.

COUNT IV INDUCING INFRINGEMENT UNDER 35 U.S.C. §271(f)

- 68. Plaintiff repeats the allegations set forth in paragraphs 1 through 39.
- 69. Defendants have supplied and/or caused to be supplied in or from the United States all or a substantial portion of the components of the invention(s) claimed in the '353 Patent, and such components are uncombined in whole or in part.
- 70. In direct violation of 35 U.S.C. § 27l(f)(1), Defendants have supplied and/or caused to be supplied such components in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '353 Patent if such combination occurred within the United States.
- 71. Defendants' inducements of infringements outside of the United States were intentional and willful.

- 72. Further, Defendants have supplied and/or caused to be supplied in or from the United States at least one component of the '353 Patent that is especially made or adapted for use in the invention(s) claimed in the '353 Patent and that is not a staple article or commodity of commerce suitable for substantial noninfringing use, and such component is uncombined in whole or in part.
- 73. In direct violation of 35 U.S.C. § 271(f)(2), Defendants have supplied and/or caused to be supplied such a component with the knowledge that the component is so made or adapted and with the intention that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States.
- 74. Such activities by Defendants were also intentional and willful.
- 75. As a result of Defendants' infringing activities, Gian has sustained damages in an amount to be proven at trial.
- 76. These indirect infringements by Defendants have caused and will continue to cause Gian irreparable harm for which there is no adequate remedy at law.

WHEREFORE, Gian is entitled to judgment:

(1) Declaring that Defendants have each directly infringed and/or indirectly infringed one or more claims of the '353 Patent;

(2) Declaring that Defendants have each induced infringement of the '353 Patent;

(3) Granting an injunction, pursuant to 35 U.S.C. § 283, preliminarily and permanently enjoining Defendants, together with their officers, directors, agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with or under or through

them, from making, selling, offering for sale, using, and/or exporting or importing any centrifuge tube assemblies that infringe the claims of the '353 Patent, or otherwise directly or indirectly committing or inducing further acts of infringement of the '353 Patent;

(4) Ordering an accounting for damages arising from Defendants' acts of direct infringement and/or indirect infringement including an accounting of the profits made by Defendants and/or lost by Gian as a result of Defendants' infringing activities, including profits on all related and convoyed products and processes;

(5) Awarding damages pursuant to 35 U.S.C. § 284, with interest;

(6) Finding that Defendants' infringement, inducement to infringe, and misrepresentations are intentional and willful and that this is an exceptional case, and granting an order awarding treble damages and reasonable attorneys' fees to Gian as permitted by 35 U.S.C. §§ 284 to 285; and,

(7) Such further relief as this Court deems proper.

Jury Demand

Plaintiff hereby demands a trial by jury on all issues properly triable to a jury.

Dated: August 19, 2016

Respectfully submitted,

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Counsel for Plaintiff

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 19, 2016, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record in this action.

<u>/s/ Stephen J. Leahu</u> Stephen J. Leahu