IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P. and GALDERMA S.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-1892 (CFC)
MEDINTER US LLC, MEDINTER LTD., ANTECO PHARMA LLC, ATTWILL MEDICAL SOLUTIONS, INC., ATTWILL VASCULAR TECHNOLOGIES LP and DERMAVANCE PHARMACEUTICALS, INC., and [redacted]	)	**JURY TRIAL DEMANDED** REDACTED - PUBLIC VERSION Original Filing Date: March 5, 2019 Redacted Filing Date: March 12, 2019
Defendants.	)	

FIRST AMENDED COMPLAINT

Plaintiffs GALDERMA LABORATORIES, L.P. and GALDERMA S.A. (collectively, "Galderma" or "Plaintiffs"), for their complaint for patent infringement against defendants MEDINTER US LLC, MEDINTER LTD, ANTECO PHARMA LLC, ATTWILL MEDICAL SOLUTIONS, INC., ATTWILL VASCULAR TECHNOLOGIES LP, DERMAVANCE PHARMACEUTICALS, INC. and [redacted] (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 6,716,251 ("the '251 patent") (Ex. A) and 7,731,758 ("the '758 patent") (Ex. B) (collectively, "the Patents-in-Suit"). Galderma markets and sells SCULPTRA® Aesthetic and SCULPTRA® (collectively, "SCULPTRA®") in the U.S. and in other countries around the world. SCULPTRA® is an injectable polylactic acid formulation used to correct wrinkles and folds in human skin. This action arises from Defendants' manufacture, use, offer for sale, and sale of DERMA VEIL

CUTANEOUS BIO-STIMULANT ("DERMA VEIL")—an injectable dermal filler product also made of a polylactic acid formulation that competes directly with SCULPTRA® and infringes the Patents-in-Suit as described below. As set forth herein, Defendants both directly and indirectly infringe the Patents-in-Suit, and such infringement is willful.

PARTIES

2. Galderma Laboratories, L.P. is a Texas limited partnership with its principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

3. Galderma S.A. is a Swiss company with its principal place of business at Avenue Gratta Paille 2, 1018 Lausanne, Switzerland.

4. Defendant Medinter US LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Medinter US LLC has a regular and established place of business at 4900 Woodway Drive, Suite 1110, Houston, Texas 77056.

5. On information and belief, Defendant Medinter Ltd. is a UK corporation having a principal place of business at 10 English Business Park, Hove East Sussex, BN3 7ET, England. On information and belief, Medinter Ltd. also conducts operations out of 4900 Woodway Drive, Suite 1110, Houston, Texas 77056, which it shares with Medinter US LLC and [redacted].

6. Defendant Anteco Pharma, LLC is a limited liability company organized and existing under the laws of the State of Wisconsin. On information and belief, Anteco Pharma, LLC has a principal place of business at 925 Development Dr., Lodi, Wisconsin 53555. On November 16, 2017, Attwill Medical Solutions, Inc. and/or [redacted]

[redacted] purchased all of the assets of Anteco Pharma, LLC.

7. Defendant Attwill Vascular Technologies LP is a limited partnership organized and existing under the laws of the State of Delaware. On information and belief, Attwill Vascular Technologies LP has a principal place of business at 925 Development Dr., Lodi, Wisconsin 53555.

8. Defendant Attwill Medical Solutions, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Attwill Medical Solutions, Inc. has a principal place of business at 925 Development Dr., Lodi, Wisconsin 53555. Attwill Medical Solutions, Inc. is a division of Attwill Vascular Technologies LP, [redacted]

9. Defendant DermAvance Pharmaceuticals, Inc. ("DermAvance") is a corporation organized and existing under the laws of the State of Delaware. On information and belief, DermAvance has a principal place of business at 274 W. Lancaster Ave., Malvern, Pennsylvania 19355.

10. [redacted]

JURISDICTION AND VENUE

11. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271 *et seq*. relating to Defendants' manufacture, use, offer for sale and sale, both directly and indirectly, of DERMA VEIL, an injectable dermal filler used in

humans to treat wrinkles and for other aesthetic purposes. Galderma will also seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201-2202 that Defendants' future manufacture, use, offer for sale, sale in the U.S., or importation into the U.S. of DERMA VEIL will infringe the '758 patent and injunctive relief against that infringement.

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

13. This Court has personal jurisdiction over Defendants consistent with the Due Process Clause of the United States Constitution and the Delaware Long-Arm Statute.

14. This Court has personal jurisdiction over [redacted]

15. This Court has personal jurisdiction over Medinter US LLC because Medinter US LLC is a limited liability company organized and existing under the laws of the State of Delaware with a registered agent in the State of Delaware located at 3511 Silverside Road, Suite 105, Wilmington, Delaware 19810. Thus, Medinter US LLC resides within, and has consented to, personal jurisdiction within this District. Medinter US LLC is listed as the specification developer and the U.S. manufacturer for DERMA VEIL in the U.S. Food and Drug Administration ("FDA") Establishment Registration & Device Listing database with an FEI Number 3010201080. (Ex. D, FDA Registration.) Medinter US LLC has committed acts of patent infringement that have led and/or will lead to foreseeable harm and injury to Galderma, such as, for example, by directly and/or indirectly making, selling, offering for sale, and/or using DERMA VEIL, where such activities have infringed one or more claims of the Patents-in-Suit. On information and belief, Medinter US LLC, directly, through intermediaries, and/or in concert with [redacted] and/or Medinter Ltd., has manufactured DERMA VEIL out of its facilities, including 4900 Woodway Drive, Suite 1110, Houston, Texas 77056, which it shares with [redacted] Medinter Ltd., for international sale and distribution.

16. This Court has personal jurisdiction over Medinter Ltd. because it is in the business of manufacturing, marketing, using, selling and/or offering for sale infringing DERMA VEIL in the United States, directly and/or through its wholly-owned subsidiary Medinter US LLC., which is incorporated in this district. Medinter Ltd., jointly and in concert with Medinter US LLC, manufactures DERMA VEIL out of its U.S. facilities, including 4900 Woodway Drive, Suite 1110, Houston, Texas 77056, which it shares with Medinter US LLC [redacted], for international sale and distribution. On information and belief, Medinter Ltd. and Medinter US LLC lack corporate separateness, operate as an integrated, unitary business, and share the same

address and management, including [redacted] Brenda J. Farrington. This Court also has personal jurisdiction over Medinter Ltd. at least pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Galderma's claims arise under federal law; (b) Medinter Ltd. is a foreign company not subject to jurisdiction in any state's courts of general jurisdiction; and (c) exercise of jurisdiction comports with due process. On information and belief, Medinter Ltd. has sufficient contacts with the United States as a whole, including but not limited to the manufacture of the DERMA VEIL product in Houston, Texas. In addition, Medinter Ltd.'s U.S. affiliate, Medinter US LLC, is a Delaware company.

17. In addition, Medinter Ltd. is the applicant for three trademark applications pending before the United States Patent and Trademark Office for the mark "DERMA VEIL CUTANEOUS BIO-STIMULANT." These applications bear Serial Numbers 87203442, 87203418, and 87203455, and state that DERMA VEIL was first used in commerce on October 9, 2014. On information and belief, these marks are used by Medinter Ltd. in connection with the manufacture and sale of DERMA VEIL in the U.S. In addition, on information and belief, these marks will be used in connection with future promotion and sales of DERMA VEIL for use by patients in the U.S. upon FDA approval of the DERMA VEIL product. (Ex. E, Clinicaltrials.gov.) Thus, Medinter Ltd. has committed acts of patent infringement that have led and/or will lead to foreseeable harm and injury to Galderma, such as, for example, by directly and/or indirectly making, selling, offering for sale, and/or using DERMA VEIL, where such activities have infringed one or more claims of the Patents-in-Suit.

18. This Court has personal jurisdiction over Anteco Pharma, LLC because, on information and belief, it is wholly owned and controlled by Attwill Vascular Technologies LP, and/or Attwill Medical Solutions, Inc. which are incorporated in Delaware. On information and

belief, Anteco Pharma, LLC now operates as an integrated, unitary business with Attwill Medical Solutions, Inc., a Delaware corporation, since Attwill Vascular Technologies LP acquired Anteco Pharma, LLC on November 16, 2017. Anteco Pharma, LLC, Attwill Vascular Technologies LP, and Attwill Medical Solutions, Inc. all share the same address of 925 Development Drive, Lodi, Wisconsin 53555. On information and belief, Attwill Medical Solutions, Inc. and/or Attwill Vascular Technologies LP, which are incorporated in Delaware, direct and control Anteco Pharma, LLC, receive financial profits based on the sales made by and through Anteco Pharma, LLC, and otherwise operate as an integrated, unitary business lacking corporate separateness. DERMA VEIL Instructions for Use, as well as the DERMA VEIL vial label, indicate that Anteco Pharma, LLC manufactures some or all of the DERMA VEIL product, and benefits financially by selling and/or otherwise providing the same to Medinter Ltd. (*See* Ex. F, DERMA VEIL Instructions for Use ("Manufactured by Anteco Pharma for Medinter, Ltd"); Ex. G, DERMA VEIL Vial Label ("Made in USA" "Anteco Pharma, LLC . . . Manufactured for Medinter, Ltd.").) Thus, Anteco Pharma, LLC has committed acts of patent infringement that have led and/or will lead to foreseeable harm and injury to Galderma, such as, for example, by directly and/or indirectly making some of all of DERMA VEIL, where such activities have infringed one or more claims of the Patents-in-Suit.

19. The Court has personal jurisdiction over Attwill Medical Solutions, Inc. because Attwill Medical Solutions, Inc. is a Delaware corporation with a registered agent in the State of Delaware located at 1209 Orange Street, Wilmington, Delaware 19810. Thus, Attwill Medical Solutions, Inc. resides within, and has consented to, personal jurisdiction within this District. On information and belief, Attwill Medical Solutions, Inc. now operates as an integrated, unitary business with Anteco Pharma, LLC and manufactures some or all of the DERMA VEIL product,

and benefits financially by selling and/or otherwise providing the same to Medinter Ltd. Thus, Attwill Medical Solutions, Inc. has committed acts of patent infringement that have led and/or will lead to foreseeable harm and injury to Galderma, such as, for example, by directly and/or indirectly making some or all of DERMA VEIL, where such activities have infringed one or more claims of the Patents-in-Suit.

20. This Court has personal jurisdiction over Attwill Vascular Technologies LP because Attwill Vascular Technologies LP is organized and existing under the laws of the State of Delaware with a registered agent in the State of Delaware located at 919 North Market Street, Suite 950, Wilmington, Delaware 19810. Thus, Attwill Vascular Technologies LP resides within, and has consented to, personal jurisdiction within this District. Attwill Vascular Technologies LP has committed acts of infringement that have led and/or will lead to foreseeable harm and injury to Galderma by directing and controlling the activities of its subsidiaries and authorized agents, Anteco Pharma, LLC and Attwill Medical Solutions, Inc., which on information and belief manufactures some or all of the DERMA VEIL product, and benefits financially by selling and/or otherwise providing the same to Medinter Ltd. On information and belief, Attwill Vascular Technologies LP directs and controls Attwill Medical Solutions, Inc., and Anteco Pharma, LLC, or otherwise operates as an integrated, unitary business lacking corporate separateness at least because Attwill Vascular Technologies LP, Attwill Medical Solutions, Inc., and Anteco Pharma, LLC all share the same address, and share overlapping management, including but not limited to William Jackson (Chief Financial Officer) and Attilio DiFiore (Chief Scientific Officer).

21. The Court has personal jurisdiction over DermAvance because it is a corporation organized and existing under the laws of the State of Delaware with a registered agent in the

State of Delaware located at 108 West 13th Street, Wilmington, Delaware 19810. Thus, DermAvance resides within, and has consented to, personal jurisdiction within this District. On information and belief, DermAvance has committed acts of infringement that have led and/or will lead to foreseeable harm and injury to Galderma, such as, for example, by forming an alliance with Medinter US LLC and/or Medinter Ltd., [redacted]

22. Further, on information and belief, DermAvance has formed an alliance with Medinter US LLC and/or Medinter Ltd. for U.S. clinical trials and to seek FDA approval of DERMA VEIL for the U.S. market, and is also using DERMA VEIL for purposes other than the conduct of clinical trials to gain FDA approval. For example, on information and belief, DermAvance uses U.S. clinical trials and research data to market and sell U.S. manufactured DERMA VEIL in foreign countries. DermAvance is the sponsor of an active clinical trial NCT02310490, entitled "DERMA VEIL Versus Sculptra for the Treatment of Nasolabial Folds Wrinkles." (Ex. E, clinicaltrials.gov). On information and belief, upon FDA approval, DERMA VEIL will be immediately offered for sale and sold throughout the U.S., including in this district, for use by patients in the U.S.

23. Venue is proper in this district under 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

THE PATENTS-IN-SUIT

24. On April 6, 2004, the United States Patent & Trademark Office ("USPTO") duly and legally issued U.S. Patent No. 6,716,251 ("the '251 patent") titled "Implant for Subcutaneous or Intradermal Injection." A true and correct copy of the '251 patent is attached

hereto as Exhibit A. The ’251 patent was originally assigned to Aventis Pharmaceutical Holdings, and Galderma S.A. is the current assignee of the ’251 patent.

25. The ’251 patent issued from an application which is a National Stage Entry of PCT/FR98/01241 filed on June 12, 1998, which claims priority to French Patent Application No. 97-7334 filed on June 13, 1997. PCT/FR98/01241 published on December 17, 1998 as WO98/56431. The claims of the ’251 patent are generally directed to bioresorbable injectable implants for human administration. For example, claim 1 of the ’251 patent states:

> A bioresorbable injectable implant for human administration consisting essentially of: bioresorbable microspheres or microparticles suspended in a gel consisting essentially of materials of non-animal origin, said microspheres or microparticles consisting of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers.

26. The ’251 patent expired on June 12, 2018. It was valid and enforceable under United States Patent Laws during its term and when the infringement occurred.

27. Keith A. Greathouse, the President and Chief Executive Officer of DermAvance, previously served as the executive vice president for Sanofi-Aventis Dermatology, where he was involved in the development and launch of SCULPTRA®. (Ex. H, Greathouse Profile; Ex. I, Greathouse NYCPM Bio.) Upon information and belief, Mr. Greathouse was intimately aware of SCULPTRA® product details, including its patent portfolio and the Patents-in-Suit, then assigned to Aventis, covering the SCULPTRA® product.

28. On information and belief, Defendants had knowledge of the ’251 patent at least as early as the release of SCULPTRA®, which is marked with the ’251 patent.

29. At all times relevant herein, until the expiration of the ’251 patent, one or more claims of the ’251 patent covered SCULPTRA®, which is marketed and sold in the U.S. by Plaintiff Galderma Laboratories L.P. Plaintiff Galderma S.A. markets and sells SCULPTRA®

internationally, and has granted Galderma Laboratories L.P. an exclusive license to the '251 patent in the U.S.

30. On June 8, 2010, the USPTO duly and legally issued U.S. Patent No. 7,731,758 ("the '758 patent") titled "Implant for Subcutaneous or Intradermal Injection." The '758 patent issued from a divisional application of the '251 patent. A true and correct copy of the '758 patent is attached hereto as Exhibit B. The '758 patent was originally assigned to Aventis Pharmaceutical Holdings, and Galderma S.A. is the current assignee of the '758 patent.

31. The claims of the '758 patent are generally directed to a reconstitutable product. For example, claim 1 of the '758 patent states:

> A reconstitutable product, which upon the addition of water becomes a bioresorbable, injectable implant product, wherein said reconstitutable product comprises a freeze-dried composition of: microparticles of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and a hydrogel precursor consisting essentially of materials of non-animal origin, wherein said precursor forms a hydrogel upon the addition of water.

32. The USPTO awarded the '758 patent with a Patent Term Adjustment of 1,784 days; thus, it remains valid and enforceable through May 1, 2023 under United States Patent Laws.

33. On information and belief, Defendants had knowledge of the '758 patent since its date of issuance, at least because of their familiarity with the state of the art, the SCULPTRA® product, and its associated patent portfolio, including but not limited to the '251 Patent.

34. At all times relevant herein, one or more claims of the '758 patent cover SCULPTRA®, which is marketed and sold in the U.S. by Plaintiff Galderma Laboratories L.P. Plaintiff Galderma S.A. markets and sells SCULPTRA® internationally, and has granted Galderma Laboratories L.P. an exclusive license to the '758 patent in the U.S.

DEFENDANTS' INFRINGING DERMA VEIL PRODUCT

35. According to the leaflet in DERMA VEIL packaging, DERMA VEIL is manufactured by Anteco Pharma, LLC for Medinter, Ltd. at 4900 Woodway Drive, Suite, 1110, Houston, Texas 77056 USA. (*See* Ex. F, Instructions for Use.)

36. According to the FDA Establishment Registration & Device Listing Database, Medinter US LLC is the establishment for DERMA VEIL, *i.e.,* registered as the specification developer and the U.S. manufacturer of export-only devices.

37. As described by the Instructions for Use, each box of DERMA VEIL contains 2 vials. Each vial of DERMA VEIL comprises 236.14 mg of a lyophilized, crystalline white powder of microparticles (40 to 60 micrometers) made of polylactic acid, glycolic acid, carboxy methyl cellulose sodium, mannitol, and polysorbate 80.

38. According to the Instructions for Use, DERMA VEIL is activated by injecting into the vial 8 ml of either Physiological Saline Solution or Sterile Water for Injection. Once activated, the formula becomes a suspension of relative viscosity. [redacted]

39. DERMA VEIL is administered by subdermal injection. The application of DERMA VEIL leads to diminishing skin depressions such as wrinkles, creases, and minor scars.

DEFENDANTS' COMMERCIALIZATION OF INFRINGING DERMA VEIL

40. The underlying PCT application that supports the Patents-in-Suit published on December 17, 1998 as WO98/56431. [redacted] The '251 Patent issued April 6, 2004. The application that led to the '758 Patent published on September 30, 2004 as U.S. Pub. No. 2004/0191323.

41. [redacted]

42. [redacted]

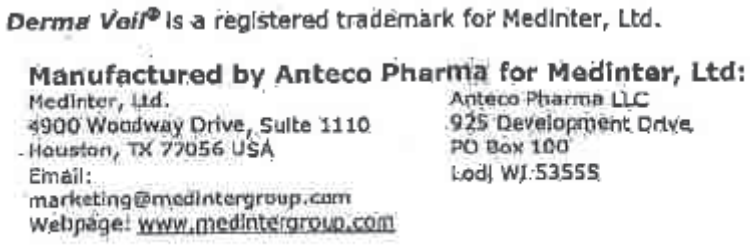
[redacted]

43. [redacted]

44. On information and belief, Defendants Medinter Ltd. and Medinter US LLC knew or should have known of the Patents-in-Suit no later than their issuance date, for example, due to knowledge of the state of the art, [redacted]. At the latest, Defendants Medinter Ltd. and Medinter US LLC learned of the Patents-in-Suit on November 29, 2018, when the Original Complaint was filed in this action. (D.I. 1.)

45. Defendants Medinter Ltd. and Medinter US LLC manufacture infringing DERMA VEIL in the United States for international commercial distribution. Additionally, on information and belief, Medinter Ltd. and Medinter US LLC use, have used, induce, and encourage contract manufacturers, such as Anteco Pharma LLC, Attwill Medical Solutions, Inc., Attwill Vascular Technologies LP, and others to assist in its manufacture of the infringing DERMA VEIL product with knowledge of, and a specific intent to infringe the Patents-in-Suit. On information and belief Anteco Pharma LLC, Attwill Medical Solutions, Inc., Attwill Vascular Technologies LP, and other contract manufacturers have profited financially by manufacturing, selling, and offering for sale infringing DERMA VEIL product at least to Medinter Ltd. and/or Medinter US LLC for international sale and distribution. This is evidenced at least by the

Instructions for Use for infringing DERMA VEIL, which identify Medinter Ltd. and Anteco Pharma LLC as U.S. manufacturers (*see* Ex. F, reproduced in part below):


Derma Veil® is a registered trademark for Medinter, Ltd.

Manufactured by Anteco Pharma for Medinter, Ltd:

Medinter, Ltd.
4900 Woodway Drive, Suite 1110
Houston, TX 77056 USA
Email:
marketing@medintergroup.com
Webpage: www.medintergroup.com

Anteco Pharma LLC
925 Development Drive
PO Box 100
Lodi WI 53555

46. On information and belief, Defendants Anteco Pharma LLC, Attwill Medical Solutions, Inc. and Attwill Vascular Technologies LP knew or should have known of the Patents-in-Suit on their issuance date, for example, due to knowledge of the state of the art, and communications with Medinter Ltd. and/or Medinter US LLC who had knowledge of the Patents-in-Suit. At the latest, Defendants Anteco Pharma LLC, Attwill Medical Solutions, Inc. and Attwill Vascular Technologies LP learned of the Patents-in-Suit on November 29, 2018, when the Original Complaint was filed in this action. (D.I. 1.)

47. On information and belief, DERMA VEIL manufactured in the U.S. has been and is currently being offered for sale and sold in foreign countries, including certain Latin American and Asian countries, for example, in Hong Kong. An example of such infringing manufacture is evidenced by vials of DERMA VEIL, which were acquired commercially outside of the United States, that indicate "MADE IN USA" by Anteco LLC for Medinter Ltd. (*See* Ex. G, reproduced below.)

48. On information and belief, Defendants have made, used, offered for sale and sold infringing DERMA VEIL product for commercial sale and distribution outside of the United States.

49. [redacted]

50. [redacted] as evidenced at least by DermAvance's marketing and advertising of DERMA VEIL through DermAvance's CEO in Asia.

51. [redacted]

52. [redacted]

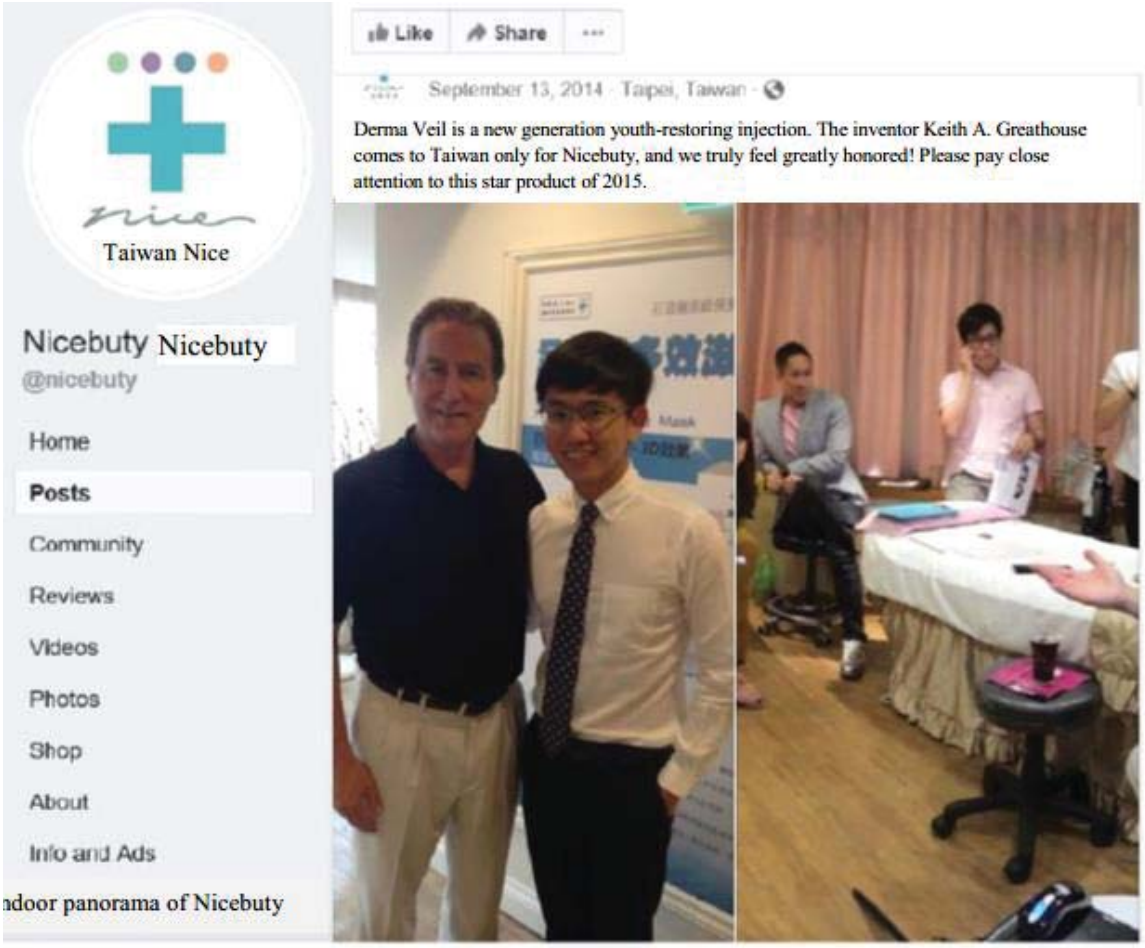
53. Keith A. Greathouse, the President and Chief Executive Officer of DermAvance, previously served as the executive vice president for Sanofi-Aventis Dermatology, where he was involved in the development and launch of Galderma's competing SCULPTRA® product. (Ex. H, Greathouse Profile; Ex. I, Greathouse NYCPM Bio.) Upon information and belief, Mr. Greathouse was intimately aware of SCULPTRA® product details, including the Patents-in-Suit, then assigned to Aventis, covering the SCULPTRA® product.

54. On information and belief, DermAvance knew or should have known of the Patents-in-Suit no later than their issuance date, at least due to Mr. Greathouse's knowledge of the state of the art and familiarity with the SCULPTRA® patent portfolio, [redacted]. At the latest, Defendant DermAvance learned of the Patents-in-Suit on November 29, 2018, when the Original Complaint was filed in this action. (D.I. 1.)

55. [redacted]

56. On information and belief, Mr. Greathouse, the founder, President and Chief Executive of DermAvance, has been promoting the sale of DERMA VEIL in Asia, including Hong Kong and Taiwan, since at least 2014. Such DERMA VEIL is manufactured in the U.S., resulting in lost sales and profits suffered by Galderma.

57. Mr. Greathouse of DermAvance actively travels internationally to advertise and promote the DERMA VEIL product manufactured in the United States by Medinter Ltd. and Medinter US LLC. For example, on information and belief, in September 2014, Mr. Greathouse marketed and promoted DERMA VEIL in Taipei, Taiwan during presentations at the Nicebuty company, where he was regarded as the "inventor" of DERMA VEIL. (Ex. K, Official Translation of Taipei Interview Facebook Post, reproduced below.)



58. On information and belief, in 2015, Mr. Greathouse marketed and promoted DERMA VEIL in Hong Kong. For example, Mr. Greathouse conducted promotional interviews with Yoko Tsang and others where he advertised that "Derma Veil is the best collagen stimulator in the current market" and "[a]ll of the Derma Veil products are produced in facilities in the U.S. which are in compliance with GMP, and are on the FDA Establishment Registration & Device listing. So the quality is absolutely guaranteed." (*See* Ex. L, Official Translation of Greathouse Elle Blog Hong Kong Interview.) During these interviews, Mr. Greathouse explained the use and efficacy of DERMA VEIL, and encouraged the use and sale of DERMA VEIL.

59. On information and belief, Mr. Greathouse travels internationally to promote and advertise DERMA VEIL, and encourage its sale and use, because DermAvance stands to profit financially through sales in the U.S. upon FDA approval. (*See, e.g.,* Ex. N.) On information and belief, neither DermAvance, nor Mr. Greathouse individually, have a direct financial stake in the international sales of DERMA VEIL other than to facilitate international recognition and success to benefit its sales of DERMA VEIL in the United States after FDA approval. Accordingly, on information and belief, DermAvance, through Mr. Greathouse, seeks to maximize the international sale and distribution of DERMA VEIL so that it receives international recognition and success by the time DERMA VEIL is approved by the FDA in the United States. DermAvance and Mr. Greathouse serve to benefit from increased U.S. sales upon FDA approval if the DERMA VEIL product receives such international recognition and success.

60. On information and belief, DermAvance knowingly and actively induces and encourages Medinter Ltd. and Medinter US LLC, with knowledge of and specific intent to infringe the Patents-in-Suit, to manufacture, and to increase manufacture of additional units, of infringing DERMA VEIL product in the United States for distribution internationally.

DermAvance actively encourages Medinter Ltd. and Medinter US LLC to increase its international sales through increased U.S. manufacture so that they can potentially maximize profits once DERMA VEIL receives FDA approval for sale in the United States. On information and belief, DermAvance, through Mr. Greathouse or other employees, has encouraged Medinter Ltd. and Medinter US LLC, through non-public written or verbal communications, to increase its United States manufacture of infringing DERMA VEIL for international distribution to boost the global recognition of DERMA VEIL to maximize U.S. sales upon FDA approval. [redacted]

61. [redacted]

62. DERMA VEIL competes with Galderma's SCULPTRA® product internationally, including in Latin America and in Asia, and will directly compete with SCULPTRA® in the U.S. including in this district once DERMA VEIL is approved by the FDA for use by patients in the U.S. In fact, DERMA VEIL's clinical trial expressly compares the SCULPTRA® product and is

called "DERMA VEIL Versus Sculptra for the Treatment of Nasolabial Folds Wrinkles." (Ex. D, clinicaltrials.gov)

63. For example, on information and belief, DERMA VEIL product manufactured in the U.S. has been sold in Hong Kong since at least 2014. Such Hong Kong sales by Defendants of DERMA VEIL made in the U.S. have damaged Galderma because they have lost sales and profits in Hong Kong from SCULPTRA® product that they otherwise would have sold but for Defendants' U.S. infringement. Likewise, on information and belief, Galderma has lost SCULPTRA® sales and profits in other Asian countries and Latin America due to Defendants' infringing acts in the U.S. Therefore, Galderma's loss of sales were the foreseeable result of Defendants' U.S. infringement.

64. According to www.dermaveil.com.hk, "Manufactured in the US" and "Registered with FDA" are prominently displayed in the advertising materials and/or all packaging for DERMA VEIL in Hong Kong to differentiate DERMA VEIL from similar products and to demonstrate the superiority of DERMA VEIL. (*See* Ex. M, www.dermaveil.com.hk.)

65. On information and belief, Cos Therapy Ltd. is the exclusive DERMA VEIL distributor in Hong Kong, receives U.S. manufactured product from Medinter Ltd. and/or Medinter US LLC, and has stated that (a) DERMA VEIL is supported by a large amount of clinical data supporting its safety and effectiveness; (b) is recognized as a medical device by the U.S. FDA Establishment Registration & Device Listing Number 3010201980; and (c) meets the U.S. cGMP and International ISO grade 7 health product production standards.

66. On information and belief, Defendants are actively seeking approval of DERMA VEIL in other Asian countries, including in Taiwan. Galderma S.A. markets and sells

SCULPTRA® in Taiwan and will suffer damages if Defendants are allowed to sell the infringing DERMA VEIL made in the U.S. in Taiwan.

67. DermAvance is actively seeking U.S. FDA approval for DERMA VEIL by having initiated a clinical trial on December 8, 2014. DermAvance is the sponsor for currently active clinical trial NCT02310490, entitled "DERMA VEIL Versus Sculptra for the Treatment of Nasolabial Folds Wrinkles." (*See,* Ex. E, clinicaltrials.gov).

68. DermAvance has undertaken the clinical trial for DERMA VEIL for purposes beyond submission for FDA approval. On information and belief, the data from the clinical trial has been and is continuing to be used to support the safety and effectiveness claims of DERMA VEIL by the Defendants in differentiating DERMA VEIL product from its competitors (such as SCULPTRA®) and in promoting DERMA VEIL product sales outside the U.S. On information and belief, when asked about safety standards of DERMA VEIL during a Hong Kong interview, Mr. Greathouse stated that DERMA VEIL was manufactured under U.S. GMP standards and passed FDA Establishment Registration and Device Listing, and therefore, the quality of DERMA VEIL is absolutely guaranteed. (Ex. L.)

69. On information and belief, the DERMA VEIL used for clinical trial NCT02310490 is manufactured in the U.S., but the amount of DERMA VEIL manufactured by Medinter US LLC and Medinter Ltd. in the U.S. significantly exceeds the amount required for the conduct of the U.S. clinical trial to support FDA approval.

70. Consequently, Defendants have engaged in infringing activity directed toward making, offering for sale, selling, or using DERMA VEIL in the U.S., and have been making meaningful preparation for the FDA approval and launch of DERMA VEIL in the U.S. Further, on information and belief and in light of the significant investment in the clinical trial and

international distribution of DERMA VEIL, Defendants are unlikely to cease infringement despite the filing of this lawsuit. Moreover, Galderma will seek a declaratory judgment that Defendants' future manufacture, sale, offer for sale, use, or importation of DERMA VEIL in the U.S. will infringe the '758 patent and injunctive relief against that infringement.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,716,251

71. Galderma incorporates by reference paragraphs 1-70 as if fully set forth herein.

72. As described above, DERMA VEIL is an injectable implant for human administration that is made of polylactic acid, glycolic acid, carboxy methyl cellulose sodium, mannitol, and polysorbate.

73. During the term of the '251 patent, Defendants manufactured, used, offered for sale, sold in the U.S., and exported from the U.S. the DERMA VEIL product, which infringed at least one claim of the '251 patent in violation of 35 U.S.C. § 271(a). More specifically, Defendants directly infringed at least claims 1, 4-7, 10, 11, 14-18, and 20 of the '251 patent in violation of 35 U.S.C. § 271(a), by making, having made, using, offering to sell, and selling DERMA VEIL in the U.S. As explained above, Medinter US LLC and Medinter Ltd, manufactured in the U.S. and exported DERMA VEIL for commercial exploitation without authority, which infringed at least claims 1, 4-7, 10, 11, 14-18, and 20 of the '251 patent. Anteco Pharma LLC, Attwill Medical Solutions, Inc., and Attwill Vascular Technologies LP, manufactured, sold and offered for sale some or all of DERMA VEIL without authority, which infringed at least claims 1, 4-7, 10, 11, 14-18, and 20 of the '251 patent.

74. For example, the Instructions for Use describe, *inter alia*, the size of DERMA VEIL microparticles as between 40 to 60 micrometers. (*See* Ex. F, Instructions for Use.) The

Defendants' manufacture, use, offers for sale and sales of DERMA VEIL in the U.S. have therefore infringed at least claims 4 and 5 of the '251 patent.

75. Further, the Instructions for Use describe DERMA VEIL as a lyophilized low viscosity, non-toxic, bioabsorbable and biodegradable material. (*See* Ex. F, Instructions for Use.) The Defendants' manufacture, use, offers for sale, and sales of DERMA VEIL in the U.S. have therefore infringed at least claims 6, 10, and 11 of the '251 patent.

76. On information and belief, during the term of the '251 patent, Defendants knowingly and intentionally induced infringement of the '251 patent under 35 U.S.C. § 271(b) by actively encouraging others to directly infringe the '251 patent, such as by actively encouraging others to make, use, offer for sale, and/or sell without authority. [redacted] Also for example, on information and belief, DermAvance actively and knowingly encouraged Medinter Ltd. and/or Medinter US LLC to manufacture, or increase manufacture of additional units, of infringing DERMA VEIL in the United States for international commercial sale and distribution, with knowledge of and specific intent to infringe the '251 Patent. On information and belief, Defendants knew that DERMA VEIL infringed as least claims 1, 4-7, 10, 11, 14-18, and 20 of the '251 patent.

77. On information and belief, Defendants had knowledge of the '251 patent during its term, copied the SCULPTRA® product, and their infringement was deliberate, egregious, willful, and in reckless disregard of the valid patent claims of the '251 patent, entitling Galderma to enhanced damages under 35 U.S.C. § 284.

78. Galderma has been injured by and has suffered substantial damages, in an amount not yet determined, as a result of Defendants' infringement of the '251 patent.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,731,758

79. Galderma incorporates by reference paragraphs 1-78 as if fully set forth herein.

80. During the term of the '758 patent, Defendants have manufactured, used, offered for sale, sold, and exported, and are currently manufacturing, using, offering for sale and selling in the U.S., and exporting from the U.S. the DERMA VEIL product to be used for human administration. Such conduct infringes at least one claim of the '758 patent in violation of 35 U.S.C. § 271(a).

81. More specifically, Defendants have directly infringed at least claims 1-6, and 9-12 of the '758 patent in violation of 35 U.S.C. § 271(a), by making, having made, using, offering to sell, and selling DERMA VEIL in the U.S. As explained above, Medinter US LLC and Medinter Ltd, manufacture in the U.S. and export DERMA VEIL for commercial exploitation, which infringes at least claims 1-6, and 9-12 of the '758 patent, without authority. Anteco Pharma LLC, Attwill Medical Solutions, Inc., and Attwill Vascular Technologies LP, manufacture, sell and offer for sale some or all of DERMA VEIL without authority, which infringes at least claims 1-6, and 9-12 of the '758 patent.

82. Further, the Instructions for Use describe DERMA VEIL as an injectable implant for human administration that is activated by injecting into the vial of DERMA VEIL 8 ml of either Physiological Saline Solution or Sterile Water for Injection and is made of polylactic acid, glycolic acid, carboxy methyl cellulose sodium, mannitol, and polysorbate. (*See* Ex. F, Instructions for Use.) Thus, the manufacture, use, offers for sale, and sales of DERMA VEIL in the U.S. infringe at least claims 1, 3-6, 9, and 10 of the '758 patent.

83. DERMA VEIL is a lyophilized low viscosity, non-toxic, bioabsorbable and biodegradable material. The manufacture, use, offers for sale and sales of DERMA VEIL therefore infringe at least claims 2 and 11 of the '758 patent.

84. Each box of DERMA VEIL contains 2 vials of DERMA VEIL and an Instructions for Use leaflet. The manufacture, use, offers for sale, and sales of DERMA VEIL therefore infringe at least claim 12 of the '758 patent.

85. On information and belief, during the term of the '758 patent, Defendants knowingly and intentionally have induced, and are continuing to induce, infringement of the '758 patent under 35 U.S.C. § 271(b) by actively encouraging others to directly infringe the '758 patent, such as by actively encouraging others to make, use, offer for sale, sell, and/or import DERMA VEIL, without authority. [redacted] Also for example, on information and belief, DermAvance actively and knowingly encourages Medinter Ltd. and/or Medinter US LLC to manufacture, or increase manufacture of additional units, of infringing DERMA VEIL in the United States for international commercial sale and distribution, with knowledge of and specific intent to infringe the '758 Patent. On information and belief, Defendants knew that DERMA VEIL infringes as least claims 1-6 and 9-12 of the '758 patent.

86. On information and belief, Defendants have been aware of the '758 patent, copied the SCULPTRA® product, and Defendants' infringement is deliberate, egregious, willful, and in reckless disregard of the valid patent claims of the '758 patent, entitling Galderma to enhanced damages under 35 U.S.C. § 284.

87. Galderma has been injured and has suffered substantial damages, in an amount not yet determined, as a result of Defendants' infringement of the '758 patent.

JURY DEMAND

Under Federal Rule of Civil Procedure 38, Plaintiffs demand trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) a judgment that Defendants have infringed the '251 patent;

(b) a judgment that Defendants have infringed the '758 patent;

(c) a judgment permanently enjoining Defendants from further infringing the '758 patent, including injunctive relief to prevent the commercial manufacture, use, offer to sell, sale, or importation of the DERMA VEIL product;

(d) an award of damages sufficient to compensate Plaintiffs for infringement of the '251 and '758 patents, including lost profits and extraterritorial damages, together with pre- and post-judgment interest and costs in accordance with 35 U.S.C. § 284;

(f) entry of an order that Defendants' infringement has been willful, and enhanced damages pursuant to 35 U.S.C. § 284;

(g) a judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and an award to Plaintiffs of their reasonable attorney fees, costs, and expenses in this action; and

(h) such other and additional relief as the Court may deem just and proper.

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