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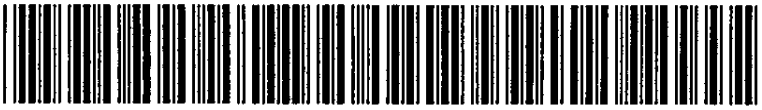

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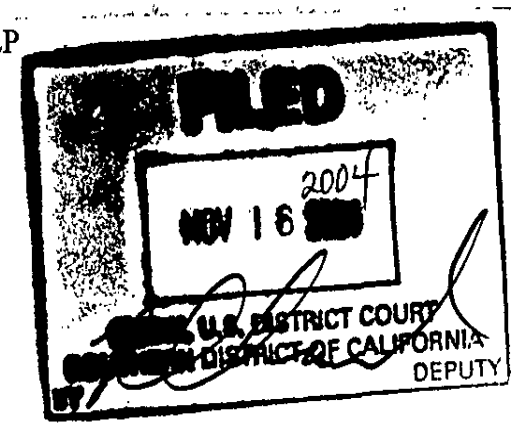

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ARTES MEDICAL USA, INC., a Delaware Corporation, Plaintiff, vs. BIOFORM MEDICAL, INC, a Delaware Corporation. Defendant.	CASE NO. 04 CV 1563 B (JFS) **~~[PROPOSED]~~ FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT; CONTRIBUTORY PATENT INFRINGEMENT; INDUCEMENT TO INFRINGE PATENT** **DEMAND FOR TRIAL JURY**

Pursuant to an Order of the Court, Plaintiff Artes Medical USA, Inc. ("Artes") hereby files its Amended Complaint against defendant BioForm Medical, Inc. ("BioForm") as follows:

1. This is a civil action for patent infringement by Plaintiff Artes. Artes seeks injunctive relief and damages, including treble damages, under the Patent Laws of the United States, Title 35, United States Code, in particular, Sections 271, 281, 283, and 284.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a) in that Plaintiff Artes is informed and believes, and thereon alleges, that Defendant BioForm has transacted and is transacting business and has regularly solicited and is soliciting business in California and specifically in this District and has purposefully availed itself of the jurisdiction of this court.

3. Defendant BioForm actively uses, sells, and offers for sale products under the trade names "Radiance™ FN", "Radiesse" and "Radiesse FN" through the United States, including California and specifically in this District, for example, for numerous surgical procedures, including for use as bone filler, as a radiographic soft tissue marker, for treatment of vocal chord insufficiency, and for the correction of skin depressions such as wrinkles, nasolabial folds, glabellar creases, marionette lines, frown lines, glabellar rhytides, labiomental folds, tear trough deficiencies, lid hollows, deep folds, depressed mouth corners, acne scars, and trauma scars.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and (c) and § 1400(b). Defendant BioForm does business, and therefore resides, in this District and Defendant BioForm's unlawful acts of infringement have occurred, and will continue to occur, in this District.

THE PARTIES

5. Plaintiff Artes is a Delaware corporation having its principal place of business at 4660 La Jolla Village Drive, Suite 825, San Diego, CA 92122.

6. Defendant BioForm is a Delaware corporation, and upon information and belief has its principal places of business at 1875 S. Grant Street, Suite 110, San Mateo, CA 94402.

BACKGROUND AND FACTS

7. On September 6, 1994, United States Patent No. 5,344,452 ("the '452 patent"), entitled "Alloplastic Implant," was duly and legally issued. Artes owns the '452 patent by virtue of an assignment dated January 22, 2000. This assignment was duly recorded in the United States Patent and Trademark Office at Reel, Frame, 010579/0948. A true and correct copy of the '452 patent, and its Certificate of Correction that issued on August 31, 2004, is attached hereto as Exhibit "A."

8. The '452 Patent is directed, *inter alia*, to a medical implant that can be injected into soft tissue, including the dermis, or skin, in order to increase the volume of the soft tissue. Soft tissue fillers covered by the patented invention have particular utility for use in plastic surgery to correct for wrinkles, lines, folds, and scars.

9. Plaintiff Artes is in the process of obtaining F.D.A. approval to manufacture and sell Artefill™, a permanent injectable filler for, *inter alia*, facial wrinkles, lines, skin depressions and scars to implement the technology disclosed in the '452 Patent.

10. On January 28, 2003, an F.D.A. Expert Advisory Panel recommended that the F.D.A. grant marketing approval for Artefill™, in the U.S. and final F.D.A. approval is anticipated in the second quarter of 2005.

DR. MARTIN LEMPERLE'S LICENSE TO BRISTOL MEYERS SQUIBB

11. In May, 1997, BioForm was granted a restricted license under the '452 patent to Bristol-Myers Squibb Company ("BMS") (the license to BMS shall hereinafter be referred to as the "BMS License"). At the time it obtained the BMS License, BMS was developing a non-polymeric, allopastic implant using calcium hydroxylapatite microspheres for the treatment of urinary incontinence. This implant utilized the microsphere technology that is covered by the claims of the '452 patent, and BMS required a license to develop and market this implant.

12. The BMS license explicitly excluded any right to make, use, sell, or offer for sale any product or material for use in plastic surgery to correct wrinkles, lines, acne scars, skin folds, and other skin conditions collectively referred to as "skin depressions". The restricted License provided:

> 1) Licensor grants to Licensee an exclusive license, even as to Licensor, to make, have made, use, sell and distribute in the Field of Use the Licensed Product as those terms are defined in this paragraph. The "Field of Use" is defined as use for any use or purpose, including but not limited to, hard and/or soft tissue augmentation, *with the exception of use in plastic surgery to compensate for skin depressions*. "Licensed Product" is defined as non-polymeric alloplastic implant material which is covered by the valid claims of the Licensed Patents."

(emphasis added)

13. Upon information and belief, Defendant BioForm claims to have been assigned the BMS license, in or about December 1999.

BREACH AND TERMINATION OF THE BMS LICENSE

14. Beginning in or about 2002, Defendant BioForm began selling products known as "Radiance™" and "Radiance™ FN" (collectively "Radiance™ products"). The Radiance™ products are soft tissue fillers which utilize the microsphere technology covered by the '452 patents. Defendant BioForm sought clearance by the FDA under 15 U.S.C. § 510(k) in 2001 to market its Radiance™ products for use as a radiographic soft tissue marker, and in 2002 to market the Radiance™ products for treatment of vocal chord insufficiency. Defendant BioForm has never received F.D.A. clearance to market any Radiance™ product for use in plastic surgery to compensate for skin depressions.

15. BioForm's website indicates that it has recently changed the name of its Radiance™ products to Radiesse ™.

16. Despite the fact that Defendant BioForm never had any license or authority to market a product for use in plastic surgery to correct for skin depressions nor any regulatory approval for this use, by late 2002 Defendant BioForm was marketing, selling, and promoting use of Radiance™ "off label" to correct for skin depressions. For example, in November 2002, upon information and belief, Defendant BioForm produced or commissioned a training video containing demonstrations featuring plastic surgeon Dr. Miles Graivier. In one of the demonstrations, Dr. Graivier demonstrates how to use Radiance™ to, in his words, "correct a depression," including "lines, wrinkles, fourroghs, depressed scars." Dr. Graivier explains how he used Radiance™:

> [T]he most common area that we use Radiance is the nasolabial fold area . . . . Another common area are the radial lip lines, both in the upper and lower lip, . . . the marionette lines, some of these cheek lines, are good areas to use the product. The glabellar lines, very common...these horizontal lines on the forehead are also easily correctable with Radiance. . . . Other areas that can be filled are the transverse radix lines, as well as just filling the soft tissue in the radix to correct a depression in that area.

17. Upon information and belief, BioForm or its agents provided copies of this video to physicians, thus promoting the use of Radiance™ as a product that could be used to compensate for skin depressions.

18. Upon information and belief beginning in 2002, and continuing to the present day, BioForm or its agents, directly solicited doctors and advised that Radiance™ could be used to compensate for skin depressions, including wrinkles.

19. Upon information and belief, in or about January 2003, BioForm attended the annual meeting of the American Academy of Cosmetic Surgery and actively promoted the use of Radiance™ to compensate for skin depressions.

20. By letter dated February 17, 2003, BioForm was notified that its marketing activities constituted a breach of the field of use restrictions in the BMS License. Artes and Dr. Lemperle demanded that Defendant BioForm observe the field of use restrictions and promptly cease all infringing marketing of Radiance™ in plastic surgery to compensate for skin depressions.

21. Thereafter, Defendant BioForm or its agents continued to market the Radiance™ products in plastic surgery to compensate for skin depressions.

22. For example, Defendant BioForm promoted Radiance™ FN to correct for skin depressions at its booth at the Combined Otolaryngological Society Meeting ("COSM") in Nashville, Tennessee on May 1-5, 2003. In its booth, Defendant BioForm displayed at least one of the videos it produced featuring Dr. Graivier demonstrating how to inject Radiance™ to correct for skin depressions. Defendant BioForm's representatives stated that Radiance™ could be used to correct facial wrinkles.

23. Upon information and belief, no later than May 2003, BioForm requested Dr. Thomas Tzikas, a Florida physician, to train other physicians how to use Radiance™ to treat skin depressions.

24. Defendant BioForm or its agents also promoted Radiance™ at its booth at the American Society of Aesthetic Surgery conference in Boston, Massachusetts from May 17-21, 2003. At this conference, upon information and belief, Defendant BioForm or its agent, participated in or directed physicians to a presentation by Dr. David Jansen, who described how Radiance™ could be used to correct nasolabial folds, facial wrinkles and radial lip lines. Dr. Jansen provided a hand-out entitled "Injection Techniques," which included detailed instructions

for injections in various parts of the face, including "Folds/Lines/Wrinkles /Depressions/Scars" and "Acne Scars/Corner of Mouth/Depressions." Defendant BioForm or its agents also explained to doctors that its Radiance products could be used as a wrinkle-filler.

25. Based upon Defendant BioForm's violations of the restricted Field of Use provisions in the BMS License, by letter of May 28, 2003, BioForm's limited license was terminated, pursuant to the terms of the License.

26. On information and belief, defendant BioForm continues to market, sell, and offer to sell Radiance™, Radiance™ FN, Radiesse™ or Radiesse™ FN products covered by the '452 patent for use in numerous surgical procedures, including for use as a radiographic soft tissue marker, for treatment of vocal chord insufficiency, as well as for the correction of skin depressions such as wrinkles, nasolabial folds, glabellar creases, marionette lines, frown lines, glabellar rhytides, labiomental folds, tear trough deficiencies, lid hollows, deep folds, depressed mouth corners, acne scars, and trauma scars.

FIRST CAUSE OF ACTION

DEFENDANT'S INFRINGEMENT OF THE '452 PATENT

27. Plaintiff Artes repeats, realleges, and incorporates by reference the allegations of paragraphs 1 through 26 above as if these paragraphs were fully set forth herein.

28. Defendant BioForm, is willfully infringing one or more claims of the '452 Patent, throughout the United States, including California and specifically in this District, by manufacturing, offering for sale and selling Radiance™, Radiance™ FN, Radiesse™ or Radiesse FN™, which are covered by one or more claims of the '452 patent.

29. Defendant's acts of infringement have been and are being committed with actual knowledge of the '452 Patent and with wanton and willful disregard for Artes' rights, rendering this an exceptional case under 35 U.S.C. § 285.

30. Plaintiff Artes has been damaged by such infringing activities and will continue to be irreparably injured unless such infringing activities are enjoined by this Court.

SECOND CAUSE OF ACTION

DEFENDANT'S INDUCING INFRINGEMENT OF THE '452 PATENT

31. Plaintiff Artes repeats, realleges, and incorporates by reference the allegations of paragraphs 1 through 30 above as if these paragraphs were fully set forth herein.

32. Plaintiff Artes is informed and believes, and thereon alleges, that Defendant BioForm is actively inducing others to infringe one or more claims of the '452 patent, throughout the United States, including California and specifically in this District, by: a) promoting the use of Radiance™, Radiance™ FN, Radiesse, or Radiesse FN for numerous procedures, including for use as a radiographic soft tissue marker, for treatment of vocal chord insufficiency, as well as for the correction of skin depressions such as wrinkles, nasolabial folds, glabellar creases, marionette lines, frown lines, glabellar rhytides, labiomental folds, tear trough deficiencies, lid hollows, deep folds, depressed mouth corners, acne scars, and trauma scars, b) instructing doctors how to use Radiance™, Radiance™ FN, Radiesse™, or Radiesse™ FN for numerous surgical procedures, including for use as a radiographic soft tissue marker, for treatment of vocal chord insufficiency, and the correction of skin depressions such as wrinkles, nasolabial folds, glabellar creases, marionette lines, frown lines, glabellar rhytides, labiomental folds, tear trough deficiencies, lid hollows, deep folds, depressed mouth corners, acne scars, and trauma scars; c) publishing and/or distributing materials that describe the use of Radiance™, Radiance™ FN, Radiesse™, or Radiesse™ FN for numerous surgical procedures, including as a radiographic soft tissue marker, for treatment of vocal chord insufficiency, and the correction of skin depressions such as wrinkles, nasolabial folds, glabellar creases, marionette lines, frown lines, glabellar rhytides, labiomental folds, tear trough deficiencies, lid hollows, deep folds, depressed mouth corners, acne scars, and trauma scars; d) requesting doctors to train other physicians to use Radiance™, Radiance™ FN, Radiesse™ or Radiesse™ FN; e) providing free samples of Radiance™, Radiance™ FN, Radiesse™, or Radiesse™ FN knowing that doctors would use the product to treat skin depressions; and, f) promoting its infringing products by paying travel expenses for doctors to lecture on using Radiance™, Radiance™ FN, Radiesse™, or Radiesse FN™ to compensate for skin depressions.

33. Plaintiff Artes is informed and believes, and the thereon alleges, that Defendant BioForm has engaged in the complained of activities with actual knowledge of the '452 patent, and knowledge that its Radiance™ and Radiesse™ products infringe the '452 patent.

34. Plaintiff Artes is informed and believes, and thereon alleges, that the complained of activities have resulted in direct infringement of one or more claims of the '452 patent.

35. Plaintiff Artes is informed and believes, and thereon alleges, that the foregoing inducement to infringe by Defendant BioForm has been willful and deliberate and will continue unless enjoined by this Court.

36. Plaintiff Artes has been damaged by such infringing activities and will continue to be irreparably injured unless such infringing activities are enjoined by this Court.

THIRD CAUSE OF ACTION

DEFENDANT'S CONTRIBUTORY INFRINGEMENT OF THE '452 PATENT

37. Plaintiff Artes incorporates by reference the factual allegations contained in paragraphs 1 through 36 above as if these paragraphs were fully set forth herein.

38. Plaintiff Artes is informed and believes, and thereon alleges, that Defendant BioForm is actively contributing to the infringement of one or more claims of the '452 patent by manufacturing, offering for sale or selling Radiance™, Radiance™ FN, Radiesse™ or Radiesse™ FN which products constitute a material part of the invention defined by one or more of the claims of the '452 patent, knowing the same to be especially made or especially adapted to practice the inventions covered by one or more claims of the '452 patent.

39. Plaintiff Artes is informed and believes, and thereon alleges, that the Radiance™, Radiance™ FN, Radiesse™ or Radiesse™ FN products manufactured, offered for sale or sold by Defendant Bioform, are not staple articles or commodities of commerce and have no substantial use that does not infringe one or more claims of the '452 patent.

40. Plaintiff Artes is informed and believes, and thereon alleges, that Defendant Bioform has engaged in the complained of activities with actual knowledge of the '452 patent.

41. Plaintiff Artes is informed and believes, and thereon alleges, that the complained of activities have resulted in direct infringement of one or more claims of the '452 patent.

42. Plaintiff Artes is informed and believes, and thereon alleges, that the foregoing contributory infringement by Defendant BioForm has been willful and deliberate and will continue unless enjoined by this Court.

43. Plaintiff Artes has been damaged by such infringing activities and will continue to be irreparably injured unless such infringing activities are enjoined by this Court.

PRAYER FOR RELIEF

Wherefore, Plaintiff Artes respectfully requests:

1. That this Court issue a judgment declaring that the '452 Patent is valid, enforceable, and that Defendant BioForm has infringed, induced infringement of the '452 patent, and/or contributed to the infringement of the '452 patent;

2. That this Court order that Defendant BioForm be preliminarily and permanently enjoined and restrained from infringing the '452 Patent;

3. That this Court order that Defendant BioForm be required to account for any and all damages caused by Defendant's complained of activities;

4. That this Court order that Defendant BioForm be required to turn over to Plaintiff Artes any and all infringing material, including but not limited to, all Radiance™, Radiance™ FN, Radiesse or Radiesse FN products, as well as marketing, promotional, or instructional materials related thereto;

5. That this Court order that Defendant BioForm be required to pay such damages as Plaintiff Artes has sustained by reason of patent infringement and that because of the willful nature of the infringement, plaintiff Artes be awarded treble damages pursuant to 35 USC § 284;

6. That this case be claimed an exceptional case within the meaning of 35 USC § 285, and reasonable attorney's fees, costs and expenses be awarded plaintiff in this action;

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7. For such other and further relief as the Court may deem just and proper.

DATED: November 10, 2004 PAUL, HASTINGS, JANOFSKY & WALKER LLP

By: _____
KURT M. KJELLAND
Attorneys for Defendant
ARTES MEDICAL USA, INC.

DEMAND FOR JURY TRIAL

Plaintiff Artes hereby demands trial by jury on all issues so triable.

DATED: November 10, 2004 PAUL, HASTINGS, JANOFSKY & WALKER LLP

By: _____
KURT M. KJELLAND
Attorneys for Defendant
ARTES MEDICAL USA, INC.