IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

ALMHA LLC Plaintiff, v. MENTOR WORLDWIDE LLC Defendant.	Civil Action No. 13-cv-2403 SAC/KGS JURY TRIAL DEMANDED

ORIGINAL COMPLAINT

This is an action for patent infringement in which Plaintiff Almha LLC makes the following allegations against Defendant Mentor Worldwide LLC.

PARTIES

1. Plaintiff Almha LLC ("Almha") is a Texas limited liability company with its principal place of business at 3301 W. Marshall Avenue, Suite 303, Longview, Texas 75604. Almha owns all right, title, and interest in United States Patent No. 6,203,570.

2. On information and belief, Defendant Mentor Worldwide LLC ("Mentor") is a Delaware corporation with its corporate headquarters and principal place of business at 201 Mentor Drive, Santa Barbara, California 93111. Mentor may be served via its registered agent for service of process, The Corporation Trust Company at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Mentor. Mentor has conducted extensive commercial activities and continues to conduct business within the State of Kansas. Mentor directly and/or through intermediaries (including other Mentor entities, subsidiaries, distributors, sales agents, partners, and others), manufactures, ships, distributes, offers for sale, sells, and/or advertises its products (including, but not limited to, the products that are accused of infringement in this lawsuit) in the United States and in the State of Kansas.

5. Mentor (directly and/or through intermediaries, including other Mentor entities, subsidiaries, distributors, sales agents, partners, and others) has purposefully and voluntarily placed one or more of its products (including, but not limited to, the products that are accused of infringement in this lawsuit) into the stream of commerce with the expectation that the products and services will be purchased by customers in Kansas. These infringing products have been and continue to be purchased by customers in Kansas. Accordingly, Mentor has committed the tort of patent infringement within the State of Kansas.

6. Mentor has committed such purposeful acts and/or transactions in the State of Kansas such that it reasonably knew and/or expected that it could be haled into a Kansas court as a future consequence of such activity.

7. Venue in the District of Kansas is proper under 28 U.S.C. §§ 1391 and 1400(b), because Mentor is subject to personal jurisdiction in this district and has committed acts of infringement in this district. Mentor makes, uses, sells, offers to sell, and/or imports infringing products within the District of Kansas, directly and/or through intermediaries, and has the requisite minimum contacts with the District of Kansas such that this venue is a fair and reasonable one.

THE PATENT-IN-SUIT

8. United States Patent No. 6,203,570 ("the '570 Patent"), entitled "Breast Implant with Position Lock," was duly and legally issued by the United States Patent & Trademark Office to John L. Baeke, M.D. ("Dr. Baeke") on March 20, 2001, after a full and fair examination. A true and correct copy of the '570 Patent is attached as Exhibit A.

9. On December 4, 2012, Almha and Dr. Baeke entered into a Patent Purchase Agreement whereby Dr. Baeke sold all right, title, and interest in the '570 Patent to Almha. Almha owns all substantial rights in the '570 Patent, including the exclusive right to sue for patent infringement, the exclusive right to recover and receive both past and future damages from infringement of the '570 Patent, the exclusive right to seek injunctive relief preventing further infringement, and all other rights associated with patent ownership. Dr. Baeke currently is the Chief Technology Officer of Almha.

10. The '570 Patent discloses an innovative breast implant prosthesis that provides fastening components to anchor the implant to retroglandular or retromuscular tissue and secure the implant in place. The patent further teaches the use of location markers to ensure correct orientation of the prosthesis during the augmentation mammoplasty procedure and provide postoperative orientation information without the use of invasive procedures.

11. The '570 Patent has been repeatedly cited in subsequent patent applications filed by leading medical devices companies, including C.R. Bard, Inc., Allergan, Inc., and Mentor Worldwide LLC.

12. By way of example only, Claim 1 of the '570 Patent recites:

> 1. A breast implant prosthesis comprising:
>
> a flexible shell of a predetermined shape composed of biocompatible material for containing a filling material and presenting an anterior area

> for orientation towards an outer skin surface and an opposed posterior area adapted to overlie internal tissue,
>
> a fastening component secured to said shell for anchoring said prosthesis, and
>
> said component comprising a material configured to secure and hold a suture therethrough to secure the component to said tissue and thereby anchor the prosthesis.

FACTUAL BACKGROUND

13. Dr. Baeke, sole inventor of the '570 Patent, is a renowned and respected plastic surgeon who retired from his clinical medical practice in 2006 and is currently the Chief Technology Officer of Almha. After graduating from the University of Kansas, School of Medicine, in 1983 and completing his plastic surgery residency at St. Francis Memorial Hospital in San Francisco in 1992, Dr. Baeke returned to Kansas to practice plastic surgery with special emphasis in breast augmentation surgery. He opened a medical practice in Overland Park, Kansas (eventually named Park Place Plastic Surgery), which he operated for fourteen years. Dr. Baeke's medical practice quickly became one of the most successful cosmetic and reconstructive practices in the United States, and he is regarded nationally as an expert and authority in breast augmentation surgery.

14. In 1992, the U.S. Food and Drug Administration ("FDA") announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and that surgeons stop implanting them while the FDA reviewed new safety and effectiveness information that had been submitted. During the entire period of the FDA moratorium, which began in January 1992, Dr. Baeke was only one of a few plastic surgeons in the United States allowed to continue implanting silicone gel implants as a Clinical Investigator.

15. During the FDA moratorium, Dr. Baeke worked with major breast implant manufacturers (including Silimed and Allergan (formerly known as Inamed Aesthetics and prior

to that known as McGhan Medical)) as a Clinical Investigator and continued to implant hundreds, if not thousands, of breast implants. Substantially all of this work occurred from Dr. Baeke's medical practice in Overland Park, Kansas.

16. Dr. Baeke has participated in six FDA clinical trials, published several papers in highly respected, peer-reviewed medical journals, has been interviewed on television, and testified before the FDA regarding silicone breast implants.

17. The genesis of Dr. Baeke's invention that led to the '570 Patent began when he discovered that breast implants in patients, which include breast tissue expanders, were rotating, flipping, or spinning from their original position (both within the immediate and long-term postoperative period). Postoperative dislodgement from its original placement created a noticeable breast deformity, particularly with the increasingly popular "teardrop" shaped implants. At that time, there was no means by which a doctor could definitively diagnose whether the breast implant had become malpositioned, short of invasive surgical procedures that would allow for physical inspection of the implant.

18. Dr. Baeke's discoveries regarding malpositioning of breast implants occurred due to his work with actual patients in his medical practice in Overland Park, Kansas. Dr. Baeke personally treated more than 25 patients who experienced malpositioning problems with breast implants both before and after the time he filed his patent application.

19. Dr. Baeke first treated a patient experiencing breast implant malpositioning in or about 1998. The patient had received teardrop implants, which were relatively new at that time, and the malpositioning was evident through clinical observation. Dr. Baeke contacted the device manufacturer regarding possible fixes for the problem, but he soon discovered that there was no known fix. Dr. Baeke, determined to help the patient, believed that the implant device could be

modified so that it could be attached permanently to tissue inside the patient's body. With the patient's consent, Dr. Baeke performed an experimental surgery on the patient in which he observed the cause of the malpositioning—the implant had flipped over and spun out of position. During the experimental surgery, Dr. Baeke attempted to attach the original implant to the patient's chest wall by placing a suture through the location tab on the original implant. The experimental surgery initially appeared to be a success, but several weeks later, a follow-up examination with the patient revealed that the implant device had flipped and rotated again.

20. Following this experimental surgery, Dr. Baeke continued to work on solutions to the malpositioning problem, and eventually he came upon the device modifications that are taught and claimed in the '570 Patent.

21. Malpositioning is a particular problem for teardrop-shaped implants because they have an asymmetrical profile when the non-implanted prosthesis is viewed resting on a horizontal surface. Dr. Baeke, at his Overland Park, Kansas medical practice, was extensively involved in implanting contoured (shaped) breast implants such as teardrop implants, and his inventions that resulted in the '570 Patent stem from that work.

22. Once these "teardrop" implants are inserted in the retroglandular or retropectoral pocket of a patient, it is difficult to correctly determine if the prosthesis is properly oriented. Typically a tab is attached by the manufacturer to the posterior surface of the prosthesis in the six o'clock position to provide a way for the physician to digitally confirm whether the prosthesis is in the orthotopic position within the pocket. However, when a transaxillary incision is used to insert the prosthesis, the surgeon is not able to reach the tab to verify correct placement of the implant and must rely on external visual inspection to ensure the proper orientation of the implant.

23. National marketing campaigns by implant manufacturers helped create a heightened demand for teardrop implants. As a result, patients expected these anatomical implants to provide a "more voluptuous" and "perfectly natural" shape. The patients' expectations were further reinforced in their minds by the higher retail price attached to the teardrop implants. Moreover, this sentiment was reinforced in the minds of breast implant surgeons due to marketing materials and professional newsletters circulated by the manufacturers and sales pitches promoted by manufacturers' field representatives.

24. Dr. Baeke, however, discovered that these teardrop-shaped implants, once they became malpositioned, would cause the patient to have extremely unnatural-looking breasts that appeared distorted and disfigured. Based on his work with his patients at his Kansas medical practice, Dr. Baeke determined that it was important to alert the medical community of the malpositioning risks associated with anatomical breast implants, which includes breast tissue expanders. He sent a letter to *Plastic and Reconstructive Surgery* (the Journal of the American Society of Plastic Surgeons; Official Organ of the American Association of Plastic Surgeons; and Official Organ of the American Society for Aesthetic Plastic Surgery), published in the September 2000 issue, that warned of the malpositioning issue. A copy of the published letter is attached as Exhibit B.

25. Dr. Baeke continued his work on the malpositioning problem, and later conducted an empirical survey consisting of a population of more than 150 patients, each of whom had been treated at Dr. Baeke's medical practice in Overland Park, Kansas. Dr. Baeke described the results of his empirical work in an academic article entitled "Breast Deformity Caused by Anatomical or Teardrop Implant Rotation" that was published in the June 2002 edition of *Plastic and Reconstructive Surgery*, a copy of which is attached as Exhibit C. A follow-up "Discussion"

of the article was published by Dr. David A. Hidalgo in which Dr. Hidalgo concluded that Dr. Baeke had taken important steps toward solving the malpositioning issue with anatomical breast implants. A copy of the Hidalgo article is attached as Exhibit D.

26. Figures 13 and 14 from the ’570 Patent illustrate breast deformities caused by rotation. Figure 13 illustrates a breast deformity caused by a breast implant that has rotated about a vertical axis and out of the original placement. Figure 14 illustrates a breast deformity caused by a breast implant that has rotated about a horizontal axis and out of the original position:

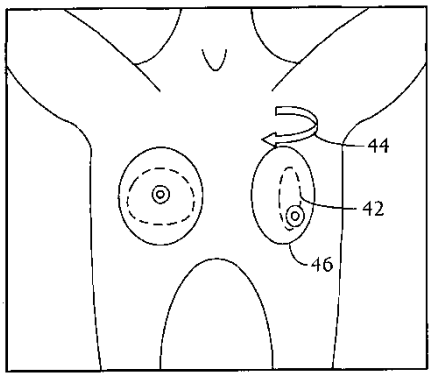

Fig. 13

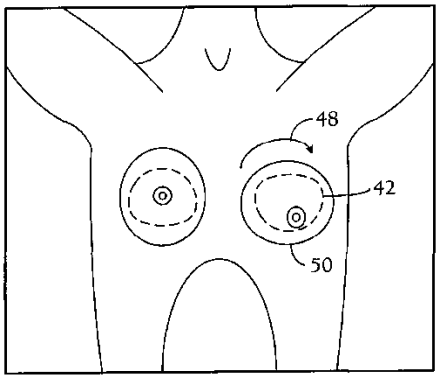

Fig. 14

27. Alternative and less-effective means of addressing the malpositioning problem have been attempted. For example, one alternative method used to address the problem of rotating shaped implants has been application of a textured coating on the teardrop implant shell to promote adherence to the body tissue and thereby prevent rotation or movement of the implant. However, it is well known to practicing breast implant surgeons that even with the textured coat, the implants can, and frequently do, still rotate.

28. The most effective means of anchoring the breast implant to avoid malpositioning is use of the apparatus taught and claimed in the ’570 Patent. In order to overcome the malpositioning problems, Dr. Baeke discovered that the breast prosthesis would be improved by

anchoring it to retroglandular or retromuscular tissue to restrict postoperative movement of the implant. Furthermore, in order to overcome the challenge of determining the orientation of the implant without direct visual inspection, Dr. Baeke conceived of using radiopaque markers to determine postoperative orientation of the prosthesis.

29. Fastening members secured to the posterior of the flexible shell of the prosthesis—and which are capable of receiving and holding a suture to secure the prosthesis to the patient's retroglandular or retromuscular tissue—would secure the breast implant. Upper and lower markers on the posterior surface of the flexible shell provide tactile and visual indicators to positively orient the prosthesis during the implantation procedure. Moreover, radiopaque markers provide postoperative location information using standard X-ray equipment to positively determine the orientation of the implant without use of a surgical procedure. This provides the patient and surgeon a non-invasive means to diagnose any postoperative implant malposition.

30. Dr. Baeke and Mentor have been involved in litigation regarding the very problem that the patented invention was developed to solve—malpositioned implants. In 2001, one of Dr. Baeke's patients brought a products liability and medical malpractice lawsuit in Kansas District Court (Johnson County) against Dr. Baeke and Mentor, complaining of rotating shaped implants. Upon information and belief, Mentor learned about the '570 Patent through discovery, meetings, or other activities relating to the litigation.

THE ACCUSED PRODUCTS

31. Mentor has sold or offered for sale at least the following products, each of which are accused in this lawsuit of infringing the '570 Patent and are referred to collectively herein as the "Accused Products." The Accused Products include, but are not limited to:

- CPX3™ CONTOUR PROFILE® Tissue Expanders with Suturing Tabs

- CPX™4 with Suture Tabs Breast Tissue Expanders
- Siltex® Saline Breast Implants

COUNT I

Infringement of U.S. Patent No. 6,203,570

32. Almha incorporates by reference as though fully set forth herein the allegations contained in paragraphs 1 through 31.

33. Almha is the lawful owner of all right, title, and interest in and to the ’570 Patent.

34. Mentor makes, uses, sells, offers to sell, and/or imports into the United States for subsequent sale or use the Accused Products, each of which directly infringes (literally and/or under the doctrine of equivalents), one or more of the claims of the ’570 Patent.

35. Mentor has (and continues to) actively, knowingly, and intentionally induce infringement of the ’570 Patent by others. More particularly, Mentor induces direct infringement by its customers who purchase the Accused Products (such as breast implant surgeons, health care delivery networks, etc.), who in turn use the Accused Products in breast implant procedures and sell the Accused Products to patients, insurance companies, Health Maintenance Organizations, and other third parties. Mentor induces the infringement of others by creating and disseminating promotional and marketing materials, instructional materials, product manuals, technical materials, and well-trained manufacturers’ field representatives that instruct others in how to commit an infringement of the ’570 Patent. Mentor’s inducement of infringement is done: (1) with knowledge of the ’570 Patent and its claims; (2) with knowledge that their customers will use, market, sell, offer to sell, and import infringing medical devices; and (3) with the knowledge and the specific intent to encourage and facilitate those infringing sales and uses of infringing medical devices through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and technical materials. On

information and belief, Mentor also conducts other training and instruction that teaches others how to commit an infringement of the ’570 Patent.

36. Mentor has (and continues to) contribute to infringement of the ’570 Patent by others. More particularly, Mentor contributes to direct infringement by its customers who purchase the Accused Products (such as breast implant surgeons, health care delivery networks, etc.), who in turn use the Accused Products in breast implant procedures and sell the Accused Products to patients, insurance companies, Health Maintenance Organizations, and other third parties. Mentor’s contributory infringement is done with: (1) knowledge of the ’570 Patent and its claims; (2) knowledge that the Accused Products constitute a material part of the inventions of the ’570 Patent; (3) knowledge that the Accused Products are especially made or adapted to infringe the ’570 Patent; and (4) knowledge that the Accused Products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

37. Upon information and belief, Mentor’s infringement of the ’570 Patent is and has been willful. Upon information and belief, prior to 2006, through litigation brought against Dr. Baeke and Mentor by Dr. Baeke’s patient, Mentor had dual notice of the ’570 Patent, and the fact that it has been infringing the ’570 Patent, well prior to the filing of this Complaint. It is also evident that Mentor had prior notice of the ’570 Patent because Mentor disclosed the ’570 Patent to the United States Patent and Trademark Office in prosecuting its own patent. For example, Mentor cited the ’570 Patent in Mentor patent 7,255,770. Moreover, Mentor has acted with a willful blindness to its infringement of the ’570 Patent.

38. Plaintiff Almha has suffered damages as a direct and proximate result of Mentor’s patent infringement. Almha is entitled to recover damages adequate to compensate it for

Mentor's infringement, not less than a reasonable royalty, and including enhanced damages for Mentor's willful infringement.

JURY DEMAND

39. Plaintiff Almha hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

40. Plaintiff Almha respectfully requests this Court to enter judgment in its favor and against Defendant Mentor, granting the following relief:

A. declaring that Mentor infringes one or more claims of the '570 Patent;

B. permanently enjoining Mentor from any further infringement pursuant to 35 U.S.C. § 283;

C. holding Mentor liable for monetary damages for such infringement, no less than a reasonable royalty, together with interest and costs as fixed by the Court pursuant to 35 U.S.C. § 284;

D. awarding enhanced damages up to three times actual damages pursuant to 35 U.S.C. § 284;

E. finding that this is an exceptional case and that Almha be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and

F. granting such other and further relief as the Court may deem just and appropriate.

DESIGNATION OF PLACE OF TRIAL

Pursuant to D. Kan. R. 40.2(a), Plaintiff designates the place of trial for this action as Kansas City, Kansas.

Dated: August 9, 2013

WAGSTAFF & CARTMELL

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